### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460



# FEPA United States Environmental Protection Office of Pesticide Programs Office of Pesticide Programs

#### Antimicrobials Division (AD)

August 6, 2015

DP BARCODE:

426355

MRID:

49573300, 49573301, 49573302, 49573303, 49573304

and 49573305

SUBJECT:

Salt Cartridge for Giselle

REG. NO .:

91386-R

DOCUMENT TYPE:

**Product Chemistry Review** 

Manufacturing-use [ ]

OR

End-use Product [X]

INGREDIENTS:

PC Code(s) 013905

7647-14-5

CAS Number Active Ingredient: Sodium Chloride

TEST LAB:

**Product Safety Labs** 

SUBMITTER:

Industrie De Nora, S.P.A.

GUIDELINE:

**OPPTS 830 Guidelines** 

Product Chemistry Group A and B

**ORGANIZATION:** 

AD\PSB\CTT

REVIEWER:

Lynette T. Umez-Eronini

APPROVED BY:

Karen P. Hicks

APPROVED DATE:

August 6, 2015

COMMENT:

The product is for non-food use.

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460



# EPA United States Environmental Protection Office of Pesticide Programs

#### Antimicrobials Division (AD)

August 6, 2015

# **MEMORANDUM**

SUBJECT:

Product Chemistry Review for EPA Reg. 91386-R

Product Name: Salt Cartridge for Giselle

DP Barcode: 426355

FROM:

Lynette T. Umez-Eronini, Chemist Lynette T. Umez-Euruniu
Chemistry and Toxicology Team

Science Branch

Antimicrobials Division (7510P)

THRU:

Karen Hicks, Team Leader

Chemistry and Toxicology Team

Product Science Branch

Antimicrobials Division (7510P)

TO:

Demson Fuller PM#32/Wanda Henson

Regulatory Management Branch II Antimicrobials Division (7510P)

Applicant:

Industrie De Nora, S.P.A.

CODE:

(A540) New Product; Non-Fast Track;

DATE DUE:

August 11, 2015

#### PRODUCT FORMULATION FROM LABEL:

Active Ingredient(s): % by wt. Sodium Chloride\* 99.86 Inert Ingredients: 0.14 Total: 100.00

<sup>\*</sup>Produces 0.6%, 0.1% and/or 0.05% available chlorine

# BACKGROUND:

The registrant, Industrie De Nora, S.p.A. has submitted an application for registration of an integrated end-use product, called Salt Cartridge for Giselle. The product is a sanitizer or disinfectant for use on hard, non-porous surfaces. The product is for non-food use.

The product chemist reviewed the following data package:

- 1. Cover letter, February 18, 2015.
- 2. Basic Confidential Statement of Formula (CSF), February 13, 2015 and August 6, 2015.
- 3. Product Label, undated.

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49573300	Industire De Nora S.p.A. (2015) Submission of Product Chemistry and Efficacy Data in Support of the Application for Registration of Salt Cartridge for Giselle(R). Transmittal of 24 Studies.
49573301	Jacoby, H. (2015) Product Chemistry in Support of Salt Cartridge for Giselle(R). Project Number: 1243/02/002, 01243/002/111/00145823/DOC/5. Unpublished study prepared by Acta Group, LLC. 19p.
49573302	Jacoby, H. (2015) Salt Cartridge for Giselle(R) - Sodium Chloride Preliminary Analysis. Project Number: 1243/02/003, 01243/002/111/00145822/DOC/5. Unpublished study prepared by Acta Group, LLC. 13p.
49573303	Bagnasco, M. (2015) Preliminary Analysis and Stability for Soleva(TM) 0.6% Solution Produced from Salt Cartridge for Giselle(R) in a Range of Water Hardness. Project Number: 1243/02/004, 01243/002/111/00150087/DOCX/4. Unpublished study prepared by Industrie De Nora, S.p.A. 25p.
49573304	Bagnasco, M. (2015) Preliminary Analysis and Stability for Soleva(TM) 0.05% Solution Produced from Salt Cartridge for Giselle(R) in a Range of Water Hardness. Project Number: 1243/02/005, 01243/002/111/00150088/DOCX/4. Unpublished study prepared by Industrie De Nora, S.p.A. 32p.
49573305	Bagnasco, M. (2015) Preliminary Analysis and Stability for Soleva(TM) 0.1% Solution Produced from Salt Cartridge for Giselle(R) in a Range of Water Hardness. Project Number: 1243/02/006, 01243/002/111/00150089/DOC/4. Unpublished study prepared by Industrie De Nora, S.p.A. 25p.

unassigned
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5. Data matrix, 4 pages, February 13, 2015.

### **FINDINGS**:

- 1. The Basic CSF, February 15, 2015 requires corrections.
- 2. Basic CSF, February 15, 2015 is obsolete and is superseded by Basic CSF, August 6, 2015.
- 3. The nominal concentration of the active ingredient on the Basic CSF, February 15, 2015 is consistent with the product label.
- 4. The 830.1800 Enforcement Analytical Method was sent via e-mail, pending assignment of an MRID and was found to be acceptable.
- Group A product chemistry data requirements applicable to end-use products have been met (see MRID# 49573301 and 49573302, Report No. 1243-02-008 and Table A below).
- Group B product chemistry data requirements applicable to end-use products have been waived and are met (see Table B below) by RED – Inorganic Halides List D Case 4051, EPA.

#### RECOMMENDATION:

 On page, 2 of label, delete \*Produces 0.6%, 0.1% and/or 0.05% available chlorine and insert \*\_\_ % available chlorine

#### CONCLUSION:

Product Science Branch of Antimicrobials Division finds Basic CSF, August 6, 2015 is acceptable and supersedes the previous Basic CSF for the same formulation. Group A and Group B Product Chemistry data requirements have been met.

# PRODUCT CHEMISTRY REVIEW

# I. CONFIDENTIAL STATEMENT OF FORMULA

a. Type of formulation and source	registration:		
Non-integrated formulation	system	Yes	[ ] No [X]
Are all TGAIs used register	red?	Yes	[ ] No [X]
<ul> <li>Integrated formulation syst</li> </ul>	em	Yes	[X] No [ ]
If "ME-TOO," specify EPA	Reg. No. of ex	isting product:	
b. Clearance of inerts for non-food The product is cleared for f §180.950.		r 40 CFR §180.	940 and
3.00.000		Yes	[ ] No [X]
c. Physical state of product:		Solid	1
d. The chemical IDs and analytical density, pH, and flammability are dB.			
J.		Yes	[ ] No [X]
e. The NCs and CLs are acceptab	le.	Yes	[X] No [ ]
f. Active ingredient Sodium Chloride	NC(%) 99.86	LCL(%) 102.86	<u>UCL(%)</u> 96.86
g. For products produced by an int	egrated formu	lation system:	
Do all impurities of toxicolo Yes [ ] No [ ]	gical significar Not applica		?
<ul> <li>Have all impurities of ≥ 0.19</li> <li>Yes [] No []</li> </ul>	% in the produ Not applica		ed?

II	PRODU	CT LABEL				
		ctive ingredient stat				
	CONFIL	ENTIAL STATEME	NT OF FORMU	JLA.	Yes [X]	No [ ]
	b. The fo	ormula contains one	of the following	g:		
		0% or more of a pe		:e:	Yes [ ]	No [X]
	• 1	.0% or more of met	hyl alcohol:		Yes [ ]	No [X]
	• 9	odium nitrite at any	level:		Yes [ ]	No [X]
	• a	toxic List 1 inert at	any level:		Yes [ ]	No [X]
	• a	rsenic in any form:	-		Yes [ ]	No [X]
		priate warning state	ement(s) regard		Not applicab y or explosive Not applicab	
	compliar	torage and disposal nce with PR Notice her uses.				
			Yes [X]	No [ ]		
		oduct requires an e sed on the 1-year st				ow the

Table A: Product Chemistry (Series 830, Group A)

Data Requirements	Acceptance of Information	MRID No.
830.1550 Product Identity <sup>1</sup>	Α	49573301
830.1600 Description of Materials	Α	49573301
830.1620 Production Process <sup>2</sup>	Α	49573301
830.1650 Formulation Process <sup>3</sup>	Α	49573301
830.1670 Formation of Impurities <sup>4</sup>	A	49573301
830.1700 Preliminary Analysis <sup>5</sup>	Α	49573302
830.1750 Certified Limits <sup>6</sup>	Α	CSF
830.1800 Enforcement Analytical Method <sup>7</sup>	Α	Report No. 1243-02- 008
830.1900 Submittal of Samples	Α	Data Matrix

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

<sup>&</sup>lt;sup>1</sup>See Confidential Appendix A for additional information.

<sup>&</sup>lt;sup>2</sup>For MP/EP products produced by an integrated formulation system.

<sup>&</sup>lt;sup>3</sup>For products from a TGAI or MP.

<sup>&</sup>lt;sup>4</sup>May be waived unless actual/possible impurities are of toxicological concern.

<sup>&</sup>lt;sup>5</sup>Five batch analysis required for products produced by an integrated formulation system.

<sup>&</sup>lt;sup>6</sup>If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.

<sup>&</sup>lt;sup>7</sup>Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

Table B: Physical and Chemical Characteristics (Series 830, Group B)

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6302 Color	NA	Keyler Harris State Control of the C	
830.6303 Physical State	W	Cited Inorganic Halide RED	
830.6304 Odor	NA		
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	NA		
830.6314 Oxidation/ Reduction; Chemical Incompatibility	W	Cited Inorganic Halide RED	
830.6315 Flammability/ Flame Extension	W	Cited Inorganic Halide RED	
830.6316 Explodability	W	Cited Inorganic Halide RED	
830.6317 Storage Stability	W	Cited Inorganic Halide RED	
830.6319 Miscibility <sup>1</sup>	W	Cited Inorganic Halide RED	
830.6320 Corrosion Characteristics	W	Cited Inorganic Halide RED	
830.6321 Dielectric Breakdown Voltage	W	Cited Inorganic Halide RED	
830.7000 pH <sup>2</sup>	W	Cited Inorganic Halide RED	
830.7050 UV/Visible Absorption	NA		
830.7100 Viscosity	W	Cited Inorganic Halide RED	
830.7200 Melting Point/Melting Range	NA		
830.7220 Boiling Point/Boiling Range	NA		
830.7300 Density/Relative Density/Bulk Density	W	Cited Inorganic Halide RED	
830.7370 Dissociation Constants in Water	NA		
830.7550/830.7560/830. 7570 Partition Coefficient	NA		
830.7840/830.7860 Water Solubility	NA		
830.7950 Vapor Pressure	NA		

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

<sup>\*</sup> Provide brief description, e.g., color – yellow or property value, e.g., density

<sup>1.25</sup> g/cc. unless otherwise indicated, the property should be at 25°C.

<sup>&</sup>lt;sup>1</sup>If product is an emulsifiable liquid

<sup>&</sup>lt;sup>2</sup>If product is dispersible with water



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

# August 06, 2015

# **MEMORANDUM**

Subject: Efficacy Review for Salt Cartridge for Giselle®; EPA File Symbol 91386-R; DB

Barcode: D426354.

From: Ibrahim Laniyan, Ph.D.

Microbiologist

**Product Science Branch** 

Antimicrobials Division (7510P)

Thru: Mark Perry, Team Leader

Product Science Branch

Antimicrobials Division (7510P)

To: Demson Fuller RM32 / Wanda Henson

Regulatory Management Branch II Antimicrobials Division (7510P)

Applicant: Industrie De Nora, S.p.A.

De Nora Tech.

7590 Discovery Lane Concord, OH 44077

### Formulation from the Label:

Salt Cartridge for Giselle®:	Active Ingredient	% by wt.
	Sodium Chloride*	. 99.86 %
	Other Ingredients:	0.14 %
	Total	

\*Produces 0.6%, 0.1%, and 0.05% available chlorine

**SOLEVATM** 

Active Ingredient	% by wt.	% by wt.	% by wt.
Sodium Hypochlorite	0.05 %	0.1 %	0.6 %
Other Ingredients:	99.95 %	99.9 %	99.4 %
		100.0 %	
	Available chlorine: 0.05 %	Available chlorine: 0.1 %	Available chlorine: 0.6 %

#### I. BACKGROUND

The product, Salt Cartridge for Giselle® (EPA File Symbol 91386-R), is a new product. The applicant, Industrie De Nora S.p.A. (De Nora), requested to register sodium chloride as a precursor chemical that De Nora intends to use in conjunction with De Nora's Giselle® machine. The Giselle® machine converts the registered precursor chemical to produce ready-to-use sodium hypochlorite solutions (SOLEVA™) for use as a sanitizer (0.05 percent and 0.1 percent concentrations) or disinfectant (0.6 percent concentration). The Giselle® technology prepares unbuffered solutions of sodium hypochlorite that pose reduced potential hazard to users because their pH are closer to neutral than buffered solutions, but the hypochlorite has a shorter shelf life. The Giselle® technology therefore allows users to produce single-use amounts of disinfectant or sanitizer for immediate use and prints an expiration sticker for each bottle of solution produced. Studies were conducted at Eurofins Biolab S.R.L., located at Via Bruno Buozzi 2, 20090 Vimodrone (MI), Italy.

This data package, identified as D426354, contained a letter from the applicant to EPA (dated February 18, 2015); sixteen studies (MRID Nos. 495733-09 through 495733-24), Statements of No Data Confidentiality Claims for all studies, Equipment Manuals for Giselle® 1.0, and the proposed labels (for "Salt Cartridge for Giselle®", SOLEVA™ 0.05%, 0.1%, and 0.6%).

#### II. USE DIRECTIONS

#### Direction For Use for Giselle®:

- Dry. Ready-to-Use
- Shake vigorously before use.
- Remove the cap and insert the cartridge in Giselle® cartridge compartment without removing the protective foil
- · Gently tap the cartridge bottom, to facilitate salt crystals flow.
- Do not use if the cartridge or the protective foil are damaged.

#### Direction For Use for SOLEVA™

Sodium Hypochlorite Solution (0.1%)

- Ready-to Use. No further dilution required.
- Limit exposure of the solution to sunlight and heat sources.
- Include time (day/hour) of SOLEVA 0.05% solution production on the bottle using the dedicated label.
- Efficacy of the solution is maintained if used within 48 hours (0.05% Solution) from production and kept in sealed bottles. Do not use 48 hours after production time. Refer to the label indicating time of production.
- SOLEVA 0.05% solution can be used as a sanitizer on a variety of bard non-porous food and non-food environmental surfaces, and non-critical care equipment surfaces. (For a complete list, refer to the manual.)
- Pre-clean heavily soiled surfaces according to the instructions below.
- Spray SOLEVA 0.05% solution directly onto the surface to be sanitized. Thoroughly wet the entire surface. Wait 2 minutes before rinsing with potable water.
- SOLEVA 0.05% solution has been tested against Staphylococcus aureus ATCC 6538 and Klebsiella pneumonia ATCC 4352 in the presence of 5% organic soil (blood serum).

# Sodium Hypochlorite Solution (0.1%)

- Ready-to Use. No further dilution required.
- Limit exposure of the solution to sunlight and heat sources.
- Include time (day/hour) of SOLEVA 0.1% solution production on the bottle using the dedicated label.
- Efficacy of the solution is maintained if used within 48 hours (0.1% Solution) from production and kept in sealed bottles. Do not use 48 hours after production time. Refer to the label indicating time of production.
- SOLEVA 0.1% solution can be used as a sanitizer on a variety of bard non-porous food and non-food environmental surfaces, and non-critical care equipment surfaces. (For a complete list, refer to the manual.)
- Pre-clean heavily soiled surfaces according to the instructions below.
- Spray SOLEVA 0.1% solution directly onto the surface to be sanitized. Thoroughly wet the entire surface. Wait 2 minutes before rinsing with potable water.
- SOLEVA 0.1% solution has been tested against Staphylococcus aureus ATCC 6538 and Klebsiella pneumonia ATCC 4352 in the presence of 5% organic soil (blood serum).

Special Cleaning Instructions Prior to Sanitization of Heavily Soiled Surfaces:

Personal Protection: Wear appropriate barrier protection such as gloves, gowns, masks, or eye covering.

Cleaning Procedure: Fecal matter/waste must be thoroughly cleaned from surface/object before sanitization by application with a clean cloth, mop, and/or sponge saturated with the sanitizer product. Cleaning is to include vigorous wiping and/or scrubbing, until all visible soil is removed. Special attention is needed for high-touch surfaces. Do not reuse soiled cloths.

#### Sodium Hypochlorite Solution (0.6%)

- Ready-to use. No further dilution required.
- Limit exposure of the solution to sunlight and heat sources.
- Include rime (day/hour) of SOLEVA 0.6% solution production on the bottle using the dedicated label
- Efficacy of the solution is maintained if used within 24 hour (0.6% Solution) from production and kept in sealed bottles. Do not use 24 hours after production time. Refer to the label indicating time of production.
- SOLEVA 0.6% solution can be used as a disinfectant on a variety of hard non-porous, food and non-food environmental surfaces, and non-critical care equipment surfaces (For a complete list, refer to the manual.)
- To kill fungi or Clostridium difficile spores, pre-clean a heavily soiled surface according to the instructions below prior to spraying SOLEVA 0.6% solution.
- Spray SOLEVA 0.6% solution directly onto the surface to be disinfected. Hold sprayer 6
  to 8 inches from the surface to be disinfected. Thoroughly wet the entire surface. Wait 10
  minutes before rinsing with potable water. Thoroughly rinse surfaces when steel or coated
  metals are treated.
- SOLEVA 0.6% kills: Staphylococcus aureus ATCC 6538, Pseudomonas aeruginosa ATCC 15442, Salmonella enterica ATCC 10708, Trichophyton mentagrophytes ATCC 9533, Poliovirus type 1 Sabin Strain Lcs2b, Feline Calicivirus F-9 ATCC V'R782, and Hepatitis C virus ATCC VR534, HIV-1 (HTLV IIIB), Clostridium difficile ATCC 43598.

Special Cleaning Instructions Prior to Disinfection of Heavily Soiled Surfaces or for *Clostridium difficile* spores:

Personal Protection: Wear appropriate barrier protection such as gloves, gowns, masks, or eye covering.

Cleaning Procedure: Fecal matter/waste must be thoroughly cleaned from surface/object before sanitization by application with a clean cloth, mop, and/or sponge saturated with the sanitizer product. Cleaning is to include vigorous wiping and/or scrubbing, until all visible soil is removed. Special attention is needed for high-touch surfaces. Surfaces in patient rooms are to be cleaned in an appropriate manner, such as from right to left or left to right, on horizontal surfaces, and top to bottom, on vertical surfaces, to minimize spreading of the spores. Restrooms are to be cleaned last. Do not reuse soiled cloths.

Infectious Materials Disposal: Materials used in the cleaning process that may contain feces/wastes are to be disposed of immediately in accordance with local regulations for infectious materials disposal.

#### III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Sporicidal Disinfectant against Clostridium difficile: The Agency has established interim guidance for the efficacy evaluation of antimicrobial products (e.g., dilutable products, ready-touse products, spray products, vapor, gases, and towelettes) that are labeled for use to treat hard. non-porous surfaces in healthcare settings contaminated with spores of Clostridium difficile. The effectiveness of such a product must be substantiated by data derived from ASTM E 2197: Standard Quantitative Carrier Test Method to Evaluate the Bactericidal, Fungicidal, Mycobactericidal, and Sporicidal Potencies of Liquid Chemical Germicides. Modifications to each test method will be necessary to specifically accommodate spores of Clostridium difficile. Because Clostridium difficile is an obligate anaerobe, testing should ensure adequate incubation conditions for the recovery of viable spores. Three product batches should be tested at or below the lower certified limit(s) (LCL) listed on the confidential statement of formula (CSF) of the product. The toxigenic strains, ATCC 43598, of Clostridium difficile must be used for testing. For towelette and spray formulations, the Agency will accept testing of the liquid expressed directly from towelettes or collected directly from spray containers using one of the quantitative methods and conditions specified above. All products should be tested with a 3-part soil load incorporated into the test inoculum by adding 25 µl of 5% bovine serum albumin, 35 µl of 5% yeast extract and 100 µl of 0.4% mucin to 340 µl of the spore suspension. Results must show a minimum 6 log reduction of viable spores in 10 minutes or less. For towelette products, wetness determination test will be used to generate the contact time. Control carrier counts must be greater than 106 spores/carrier. The titer and purity of the final spore preparation must be >108 spores/mL, and >95% spores. ASTM Standard E2839 specifies procedures for achieving the 95% purity. The acid resistance of purified spores should be assessed against 2.5 M hydrochloric acid (see ASTM Standard E2839). The spores are considered acid-resistant if a log reduction of 0-2 is exhibited following 10 minutes of exposure to 2.5 M HCl.

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments: The effectiveness of disinfectants for use on hard surfaces in hospital or medical environments must be substantiated by data derived using the AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products Test (for spray products), or the AOAC Hard Surface Carrier Test. The tests require that sixty carriers must be tested with each of

3 samples, representing 3 different product lots at the LCL, against *Staphylococcus aureus* ATCC 6538 (for effectiveness against Gram-positive bacteria), and *Pseudomonas aeruginosa* ATCC 15442 (representative of a nosocomial pathogen), [120 carriers per sample; a total of 360 carriers]. To support products labeled as "disinfectants", killing on 59 out of 60 carriers is required in AOAC Germicidal Spray Products Test to provide effectiveness at the 95% confidence level. To pass performance requirements when using AOAC Hard Surface Carrier Test, tests must result in killing in 58 out of each set of 60 carriers for *Staphylococcus aureus* ATCC 6538; 57 out of each set of 60 carriers for *Pseudomonas aeruginosa* ATCC 15442. Performance requirements when using AOAC Use-Dilution Method are killing in 57 out of each set of 60 carriers for *Staphylococcus aureus* ATCC 6538 and 54 out of each set of 60 carriers for *Pseudomonas aeruginosa* ATCC 15442. Each microbe should be tested three times. Each test should be conducted against a separate batch of product for a total of three batches. Each of the three tests should be conducted on a different day.

**Disinfectants for Use as Fungicides (Against Pathogenic Fungi):** Effectiveness of liquid disinfectants against specific pathogenic fungi must be supported by efficacy data derived from each of 2 samples representing 2 different batches at LCL, using the AOAC Fungicidal Test. **Performance requirements for this test**: the highest dilution that kills all fungal spores is the minimum effective concentration.

Alternatively, the AOAC Use Dilution Method, modified to conform with appropriate elements in the AOAC Fungicidal Test, may be employed. If the product is intended for use as a spray, the AOAC Germicidal Spray Products Test must be employed. The inoculum in the above tests must be modified to provide a concentration of at least 10<sup>6</sup> conidia per carrier. Ten carriers on each of 2 samples representing 2 different batches at LCL must be employed in the test. **Performance standard for this test:** Killing of the test microorganism on all carriers is required.

**Virucides**: The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant at LCL must be tested against a recoverable virus titer of at least 10<sup>4</sup> from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level.

**Virucides - Use of a Surrogate Virus:** For certain viruses, there are no *in vitro* systems or *in vivo* animal models (except for humans and chimpanzees). The Agency permits the testing of surrogate viruses in these cases, for example, Bovine Viral Diarrhea virus as a surrogate for human Hepatitis C virus, Duck Hepatitis B virus as a surrogate for Human Hepatitis B virus, and Feline Calicivirus as a surrogate for Norwalk virus.

Sanitizer Test (for inanimate, non-food contact surfaces): The effectiveness of sanitizers for non-food contact surfaces must be supported by data that show that the product will substantially reduce the numbers of test bacteria on a treated surface over those on an untreated control

surface. The test surface(s) should represent the type(s) of surfaces recommended for treatment on the label, i.e., porous or non-porous. Products that are represented as "one-step sanitizers" should be tested with an appropriate organic soil load, such as 5 percent serum. Tests should be performed with each of 3 product samples, representing 3 different product lots at the LCL against *Staphylococcus aureus* (ATCC 6538) and either *Klebsiella pneumoniae* (aberrant, ATCC 4352) or *Enterobacter aerogenes* (ATCC 13048 or 15038). The ASTM method states that the inoculum employed should provide a count of at least 7.5 x 10<sup>5</sup> colony forming units per carrier. Results must show a bacterial reduction of at least 99.9 percent over the parallel control within 5 minutes.

#### IV. BRIEF DESCRIPTION OF THE DATA

MRID 495733-06 "Life Cycle Testing for Soleva™ Solutions Produced by the Giselle® Equipment", by Mara Bagnasco. Completion date – January 30, 2015.

Objective

Type of Soleva solution	FAC* Lower Limit	FAC* Nominal Value	FAC* Upper Limit
0.6% (6000ppm)	0.571% (5715ppm)	0.635% (6350ppm)	0.698% (6985ppm)
0.1% (1000ppm)	0.099% (990ppm)	0.110% (1100ppm)	0.121% (1210ppm)
0.05% (500ppm)	0.048% (477ppm)	0.053% (530ppm)	0.058% (5803ppm)

(\*) FAC: Free Available Chlorine

#### Tested

Type of Soleva solution	FAC* Lower Limit for tests	FAC*Nominal Value for tests	FAC* Upper Limit for tests
0.6% (6000ppm)	0.611% (6115ppm)	0.679% (6795ppm)	0.698% (6985ppm)
0.1% (1000ppm)	0.105% (1059ppm)	0.118% (1177ppm)	0.129% (1295ppm)

(\*) FAC: Free Available Chlorine

1. MRID 495733-09 "EVALUATION OF IN VITRO QUANTITATIVE SPORICIDAL EFFICACY AGAINST Clostridium Difficile ON GISELLE AND SOLEVA SOLUTIONS", by LAURA BRAMBILLA. Study conducted at EUROFINS BIOLAB S.R.L. Study completion date – April 15, 2014. Project Number S-2013-02013 AMi.

This study was conducted against *Clostridium difficile* (spore form) (ATCC 43598). Two lots (BATCH 16-Jan-2014 h10:42 and BATCH 27-Jan-2014 h10:30) of the product, SOLEVA Solution 0.6%, were tested using the Quantitative Sporicidal Three-Step Method (TSM). Product lots were tested at 5700 ppm of Cl<sub>2</sub> obtained diluting the preparation at 6625 ppm (with tap water) in order to simulate the final concentration at the end of its shelf-life. A culture of the challenge microorganism was prepared in accordance with ASTM method specifications. Three (3) glass carriers (0.5x0.5 cm) per product lot were inoculated with 10 µL of a culture of test organism. The carriers were dried in a vacuum desiccator for 10 to 20 hours at 20-25°C. Each carrier was sprayed with the test item and left for 10 minutes contact time. After the contact time, each carrier was transferred Into a 1.5 ml tube with ice-cold neutralizer (labelled A) and then immediately transferred to a new 1.5 ml tube containing sterile distilled water at room temperature (labelled B) that was sonicated for 5 minutes. Ice-cold BBL Cooked Meat Medium was then added to the tube and the carrier is transferred to a new 1.5 ml tube (labeled C) containing BBL Cooked Meat Medium. The Tubes C were incubated in a thermostated orbital agitator at 37°C for 30 minutes in anaerobic conditions. The carrier was discarded and the surviving spores in each fraction, i.e. A,

B and C, were enumerated by serial dilution by spreading method on Columbia agar plate. The plates were Incubated for 72 hours at 37±1°C In anaerobic conditions and the total residual spore colonies were counted by adding the spores counted in Fraction A, plus spores in Fraction B and plus spores in Fraction C. The sporicidal effect of a disinfectant was calculated by subtracting the Log value of the total number spores on the disinfectant from the Log of the total number of spores in the controls. Controls included those for initial suspension count, carrier population, purity, sterility, and neutralization confirmation.

2. MRID 495733-10 "EVALUATION OF DISINFECTANT EFFICACY FOR BROAD-SPECTRUM AND HOSPITAL OR HEALTHCARE SPECTRUM ON HARD NON-POROUS SURFACES ON GISELLE AND SOLEVA SOLUTIONS," Test Organisms: *S. aureus* (ATCC 6538), *S. choleraesuis* (ATCC 10708) and *P. aeruginosa* (ATCC 15442), by Laura Brambilla. Study conducted at Eurofins Biolab S.R.L. Study completion date – November 18, 2013. Report No. S-2013-02012 AMi.

This study was conducted against *Staphylococcus aureus* (ATCC 6538), *Salmonella choleraesuis* (ATCC 10708) and *Pseudomonas aeruginosa* (ATCC 15442). Three batches (ACE-2013-00108210, ACE-2013-00108251 and ACE-2013-00108252) of the product, SOLEVA SOLUTIONS, were tested using the AOAC Official Method 961.02 - Germicidal Spray Products as Disinfectan. A use concentration of 5700 ppm of Active Cl<sub>2</sub> was prepared by dilution using tap water. Fetal calf serum was added to the culture to achieve a 5% organic soil load. Sixty (60) glass slide carriers were inoculated with 0.01 ml of suspension of the test organism and soil load (the inoculum was spread on about 6.45 cm<sup>2</sup> of the carrier using a sterile loop). The carriers were dried for 30-40 minutes at 37±1°C. Each carrier was sprayed with the product from a distance of 30.48cm for 10 seconds. The carriers were allowed to remain wet for 10 minutes at 20±1°C. After the contact time, each slide was transferred into one tube containing 20 ml of Letheen Broth to neutralize for 30 minutes at 37°C and then examined for the presence of absence or visible growth. Controls included neutralization, viability and bacteriostasis. The reported average colony forming units per carrier for the test microorganism is: *Staphylococcus aureus* 4.0x10<sup>7</sup>, *Salmonella choleraesuis* 3.7x10<sup>7</sup> *and Pseudomonas aeruginosa* 2.3 x 10<sup>7</sup>.

3. MRID 495733-11 "EVALUATION OF IN VITRO QUANTITATIVE VIRUCIDAL EFFICACY AGAINST HUMAN IMMUNODEFICIENCY VIRUS (HIV-1) ON GISELLE AND SOLEVA SOLUTIONS", by LAURA BRAMBILLA. Study conducted at EUROFINS BIOLAB S.R.L. Study completion date — February 24, 2014. Project Number S-2013-02014 AMi.

This study was conducted against Human Immunodeficiency Virus (HIV-1) using the amount of viral protein p24 to determine the viral titer. 1000pg/ml HIV-1 p24. Two lots (BATCH 27-Jan-2014 h09:50 and BATCH 27-Jan-2014 h10:02) of the product, SOLEVA Solution 0.6%, were tested according to ASTM E-1053;2011 and EPA OCSPP 810.2200 (HQ-OPPT-2009). The product was diluted with tap water from produced 6625 ppm active  $Cl_2$  to the final concentrations of 5700 ppm of active  $Cl_2$ . The stock virus culture contained a 5% organic soil load (fetal calf serum). Films of virus were prepared by spreading 0.2 ml (1000pg/ml HIV-1 p24) of virus inoculum uniformly over the bottoms of separate sterile carriers (Petri Plates of 90mm in diameter and 1cm in deep). The virus films were dried at 37°C  $\pm$  1°C until visible drying. For each lot of product, two separate dried virus films were treated with 2ml of each test solution for 10 minutes at the temperature of 22°C  $\pm$  2°C. At the end of the contact time, an ELISA test, i.e. an enzyme immunoassay for the detection of Human Immunodeficiency Virus Type 1 (HIV-1) p24 in tissue culture media, was performed for the detection of the residual viral suspension. Specifically, the

test mixture was mixed with Disruption Buffer to inactivate the virus and to release HIV-1 p24 into solution to enable detection. The microtiter wells of a 96-well plate are coated with two murine monoclonal antibodies that react with unique epitopes on HIV-1 p24 so the HIV-1 p24 Standard solutions or the test mixture were added to the wells in order to form an immune complex with the plate-bound antibodies and the p24 in solution. Unbound materials were then thoroughly washed away. Conjugate Solution containing peroxidase-conjugated human anti-p24 polyclonal antibodies, was then added and the conjugated antibodies complex with the captured HIV-1 p24 was obtained. After washing the wells to remove the unbound conjugated antibodies. Peroxidase Substrate was added to the wells. The enzyme-substrate reaction was resulted in a blue color change. Upon adding Stop Solution, the blue color was changed to yellow, and the absorbance was measured at 450 nm. There is a linear relationship between the absorbance at 450 nm and the amount of HliV-1 p24 bound to the well so the concentration of HlV-1 p24 in test mixture was determined from linear regression analysis of the standard curve. Controls included those for cytotoxicity, dried virus controls, virus titration, and neutralization.

4. MRID 495733-12 "EVALUATION OF FUNGICIDAL EFFICACY AGAINST *Trichophyton mentagrophytes* ON HARD NON-POROUS SURFACES ON GISELLE AND SOLEVA SOLUTIONS," Test Organisms: *T. mentagrophytes* (ATCC 9533), by Laura Brambilla. Study conducted at Eurofins Biolab S.R.L. Study completion date – November 18, 2013. Report No. S-2013-02016 AMi.

This study was conducted against *Trychophyton mentagrophytes* (ATCC 9533). Two lots (15-Oct-2013 h08:37 and 15-Oct-2013 h08:49)) of the product, SOLEVA SOLUTION, were tested according to the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Method 961.02. The product was diluted to 5700 ppm of Cl<sub>2</sub> with tap water. The test was performed without soiling load. Ten (10) glass slide carriers per product lot were inoculated with 0.01 mL of the suspension of the test organism (the inoculum was spread on about 6.45cm² of the carrier using a sterile loop). The carriers were dried for 30-40 minutes at 37±1°C. For each lot of product, carriers were sprayed with the product for 10 seconds at a distance of 30.48cm from the carrier surface. Each carrier remained exposed to the product for 5 minutes at 21.0±1°C. Following exposure, individual carriers were transferred to 20 mL of subculture medium (Letheen Broth) to neutralize. All subcultures were incubated for 30 minutes at 37.0°C. Following incubation and storage, the subcultures were examined for the presence or absence of visible growth. Controls included those for fungistasis and viability. The average reported initial colony forming units per carrier, for the test microorganism, is: *Trychophyton mentagrophytes* 7.0 x 10<sup>4</sup>.

5. MRID 495733-13 "EVALUATION OF DISINFECTANT EFFICACY FOR BROAD-SPECTRUM AND HOSPITAL OR HEALTHCARE SPECTRUM ON HARD NON-POROUS SURFACES ON GISELLE AND SOLEVA SOLUTIONS," Test Organisms: S. aureus (ATCC 6538), S. choleraesuis (ATCC 10708) and P. aeruginosa (ATCC 15442), by Laura Brambilla. Study conducted at Eurofins Biolab S.R.L. Study completion date – November 30, 2012. Report No. 2012/1681 AMi.

This study was conducted against Staphylococcus aureus (ATCC 6538), Salmonella choleraesuis (ATCC 10708) and Pseudomonas aeruginosa (ATCC 15442). Eleven batches (26-Sep-2012 h10:23, 26-Sep-2012 h10:50, 27-Sep-2012 h11:10, 27-Sep-2012 h11:20, 02-Oct-2012 h09:26, 02-Oct-2012 h09:49, 11-Oct-2012 h11:00, 11-Oct-2012 h11:20, 30-Oct-2012 h10:25, 31-Oct-2012 h09:10, 31-Oct-2012 h09:34) of the product, SOLEVA SOLUTIONS, were tested using the AOAC Official Method 961.02 - Germicidal Spray Products as Disinfectant. Three concentrations (1100 ppm of  $Cl_2$ , 5400 ppm of  $Cl_2$  and 6625 ppm of  $Cl_2$ ) of the product solution

were prepared by dilution and tested. Fetal calf serum was added to the culture to achieve a 5% organic soil load. Sixty (60) glass slide carriers were inoculated with 0.01 ml of suspension of the test organism and soil load (the inoculum was spread on about 6.45 cm² of the carrier using a sterile loop). The carriers were dried for 30-40 minutes at 37±1°C. Each carrier was sprayed with the product from a distance of 30.48cm for 10 seconds. The carriers were allowed to remain wet for 10 minutes at 20±1°C. After the contact time, each slide was transferred into one tube containing 20 ml of Letheen Broth to neutralize for 30 minutes at 37°C and then examined for the presence of absence or visible growth. Controls included viability, neutralizer and bacteriostasis. The reported average colony forming units per carrier for the test microorganisms at 6625 ppm, respectively, are: *Staphylococcus aureus* 2.9x10<sup>7</sup>, *Salmonella choleraesuis* 6.2x10<sup>7</sup> and *Pseudomonas aeruginosa* 2.9x10<sup>7</sup>.

6. MRID 495733-14 "EVALUATION OF FUNGICIDAL EFFICACY AGAINST Trichophyton mentagrophytes ON HARD NON-POROUS SURFACES ON GISELLE AND SOLEVA SOLUTIONS," by Laura Brambilla. Study conducted at Eurofins Biolab S.R.L. Study completion date – December 31, 2012. Report No. 2012-1682 AMi.

This study was conducted against Trichophyton mentagrophytes (ATCC 9533). Six lots (14-NOV-2012 h11:20 (Solution at 6625 ppm of Cl<sub>2</sub>) T0, 14-NOV-2012 h12:00 (Solution at 6625 ppm of Cl<sub>2</sub>) T0, 29-N0V-2012 h10:13 (Solution at 6625 ppm of Cl<sub>2</sub>) T0, 29-N0V-2012 h10:24 (Solution at 6625 ppm of Cl<sub>2</sub>) T0, 21-Dec-2012 h10:59 (Solution at 5400 ppm of Cl<sub>2</sub>) T0), and 21-Dec-2012 h11:25 (Solution at 5400 ppm of Cl<sub>2</sub>) T0) of the product, SOLEVA SOLUTION, were tested according to the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Method 961.02. The product was tested at two concentrations 6625 ppm and 5400 ppm of Cl<sub>2</sub>. The test was performed without soiling load. Ten (10) glass slide carriers per product lot were inoculated with 0.01 mL of the suspension of the test organism (the inoculum was spread on about 6.45cm<sup>2</sup> of the carrier using a sterile loop). The carriers were dried for 30-40 minutes at 37±1°C. For each lot of product, carriers were sprayed with the product for 10 seconds at a distance of 30.48cm from the carrier surface. Each carrier remained exposed to the product for 5 minutes at 21.0±1°C. Following exposure, individual carriers were transferred to 20 mL of subculture medium (Letheen Broth) to neutralize. All subcultures were incubated for 30 minutes at 37.0°C. Following incubation and storage, the subcultures were examined for the presence or absence of visible growth. Controls included those for fungistasis and viability. The average reported initial colony forming units per carrier, for the test microorganism, is: Trychophyton mentagrophytes 7.0 x 104.

7. MRID 495733-15 "EVALUATION OF IN VITRO QUANTITATIVE VIRUCIDAL EFFICACY AGAINST POLIOVIRUS ON GISELLE AND SOLEVA SOLUTIONS," Test Organism: *Poliovirus*, by Laura Brambilla. Study conducted at Eurofins Biolab S.R.L. Study completion date –October 31, 2012. Report No. 2012/1683 AMi.

This study was conducted against Poliovirus type 1 LSc-2ab (Sabin) using *Hela*: cells of human uterine carcinoma, or confluent monolayer as the host system. Four lots (02-Oct-2012 h09:15, 02-Oct-2012 h09:45, 02-Oct-2012 h09:30, 02-Oct-2012 09:55) were tested on the day of production and two lots (02-Oct-2012 h09:15 and 02-Oct-2012 h09:45) were tested at 48 hours after production of the product, SOLEVA SOLUTIONS. Testing was done according to the modified ASTM E 1053-2011 method. The product was diluted with tap water to the final concentrations of 5400 ppm of active Cl<sub>2</sub> and 1100 ppm of active Cl<sub>2</sub>. The stock virus culture contained a 5% organic soil load (fetal calf serum). Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile carriers (Petri Plates of 90mm

in diameter and 1cm in deep). The virus films were dried at  $37^{\circ}\text{C} \pm 1^{\circ}\text{C}$  until visible drying. For each lot of product, two separate dried virus films were treated with 2ml of each test solution for 10 minutes at the temperature of  $22^{\circ}\text{C} \pm 2^{\circ}\text{C}$ . After exposure, 2ml of PBS (neutralizer) was transferred onto each carrier, then the plates were scraped with a cell scraper to re-suspend the residual viral inoculum. The virus-disinfectant mixture was passed through S400 HR columns MicroSpinTM for filtration, and serial dilutions 1:10 were performed and 0.1 ml of each dilution were put on dishes with the cellular confluent monolayer (>90%), 10-fold. After 1 hour of incubation, 0.1 ml of culture Medium were added to each well. The cultures were incubated at  $37^{\circ}\text{C} \pm 1^{\circ}\text{C}$  in a humidified atmosphere of 5% CO<sub>2</sub> and scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for cytotoxicity, dried virus controls, virus titration, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. The titer of the dried virus control was 5.38 and 5.13 log<sub>10</sub>. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was  $\geq$  4.80 log<sub>10</sub> for the 1100 ppm of Cl<sub>2</sub> concentration and  $\geq$ 4.80 log<sub>10</sub> for the 5400 ppm of Cl<sub>2</sub> concentration.

8. MRID 495733-16 "EVALUATION OF IN VITRO QUANTITATIVE VIRUCIDAL EFFICACY AGAINST FELINE CALICIVIRUS ON GISELLE AND SOLEVA SOLUTIONS," Test Organism: Feline Calicivirus, by Laura Brambilla. Study conducted at Eurofins Biolab S.R.L. Study completion date –October 31, 2012. Report No. 2012/1684 AMi.

This study was conducted against Feline calicivirus (Strain F-9 (FCV); ATCC VR-782). using CRFK kidney cells; Cat (Felis catus) as the host system. Four lots (02-Oct-2012 h10:15. 02-Oct-2012 h10:45, 02-Oct-2012 h10:30, 02-Oct-2012 h10:55) were tested on the day of production and two lots (02-Oct-2012 h10:15 and 02-Oct-2012 h10:45) at 48 hours after production of the product, SOLEVA SOLUTIONS. Testing was done according to the modified ASTM E 1053-2011 method. The product was diluted with tap water to the final concentrations of 5400 ppm of active Cl<sub>2</sub> and 1100 ppm of active Cl<sub>2</sub>. The stock virus culture contained a 5% organic soil load (fetal calf serum). Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile carriers (Petri Plates of 90mm in diameter and 1cm in deep). The virus films were dried at 34°C ± 1°C until visible drying. For each lot of product, two separate dried virus films were treated with 2ml of each test solution for 10 minutes at the temperature of 22°C ± 2°C. After exposure, 2ml of PBS (neutralizer) was transferred onto each carrier, then the plates were scraped with a cell scraper to re-suspend the residual viral inoculum. The virus-disinfectant mixture was passed through S400 HR columns MicroSpinTM for filtration. and serial dilutions 1:10 were performed and 0.1 ml of each dilution were put on dishes with the cellular confluent monolayer (>90%), 10-fold. After 1 hour of incubation, 0.1 ml of culture Medium were added to each well. The cultures were incubated at 34°C ± 1°C in a humidified atmosphere of 5% CO2 and scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for cytotoxicity, dried virus controls, virus titration, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. The titer of the dried virus control was 5.88 and 5.75 log<sub>10</sub>. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was ≥ 5.34 log<sub>10</sub> for the 1100 ppm of Cl<sub>2</sub> concentration and ≥4.34 log<sub>10</sub> for the 5400 ppm of Cl<sub>2</sub> concentration.

9. MRID 495733-17 "EVALUATION OF IN VITRO QUANTITATIVE VIRUCIDAL EFFICACY AGAINST BOVINE VIRAL DIARRHEA VIRUS ON GISELLE AND SOLEVA SOLUTIONS," by Laura Brambilla. Study conducted at Eurofins Biolab S.R.L. Study completion date –October 31, 2012. Report No. 2012/1685 AMi.

This study was conducted against Bovine viral diarrhea virus ATCC VR-534, using MDBK (bovine kidney) cells as the host system. Four lots (10-0ct-2012 h09:18 (Solution at 5400 ppm of Cl<sub>2</sub>) T0, 10-0ct-2012 h09:47 (Solution at 1100 ppm of Cl<sub>2</sub>) T0, 10-0ct-2012 h09:31 (Solution at 5400 ppm of Cl<sub>2</sub>) T0. 10-0ct-2012 h09:57 (Solution at 1100 ppm of Cl<sub>2</sub>) T0) were tested on the day of production and two lots (10-0ct-2012 h09:18 (Solution at 5400 ppm of Cl<sub>2</sub>) and 10-0ct-2012 h09:47 (Solution at 1100 ppm of Cl2)) at 48 hours after production of the product, SOLEVA SOLUTIONS. Testing was done according to the modified ASTM E 1053-2011 method. The product was tested at two concentrations 5400 ppm and 1100 ppm of Cl<sub>2</sub>at T0 and T48. The stock virus culture contained a 5% organic soil load (fetal calf serum). Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile carriers (Petri Plates of 90mm in diameter and 1cm in deep). The virus films were dried at 34°C ± 1°C until visible drying. For each lot of product, two separate dried virus films were treated with 2ml of each test solution for 10 minutes at the temperature of 22°C ± 2°C. After exposure, 2ml of PBS (neutralizer) was transferred onto each carrier, then the plates were scraped with a cell scraper to re-suspend the residual viral inoculum. The virus-disinfectant mixture was passed through S400 HR columns MicroSpinTM for filtration, and serial dilutions 1:10 were performed and 0.1 ml of each dilution were put on dishes with the cellular confluent monolayer (>90%), 10-fold. After 1 hour of incubation, 0.1 ml of culture Medium were added to each well. The cultures were incubated at 34°C ± 1°C in a humidified atmosphere of 5% CO<sub>2</sub> and scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for cytotoxicity, dried virus controls, virus titration, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. The titer of the dried virus control was 5.88 and 6.13 log<sub>10</sub>. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was ≥ 4.38 log<sub>10</sub> for the 1100 ppm of Cl<sub>2</sub> concentration and ≥4.63 log<sub>10</sub> for the 5400 ppm of Cl<sub>2</sub> concentration.

10. MRID 495733-18 "EVALUATION OF SANITIZING BACTERICIDAL EFFICACY AGAINST S. aureus AND K. pneumoniae FOR NON-FOOD AND FOOD HARD NON-POROUS SURFACES ON GISELLE AND SOLEVA SOLUTIONS," Test Organisms: Staphylococcus aureus (ATCC 6538) and Klebsiella pneumonia (ATCC4352), by Laura Brambilla. Study conducted at Eurofins Biolab S.R.L. Study completion date – November 23, 2012. Report No. 2012/1686 AMi.

This study was conducted against Staphylococcus aureus (ATCC 6538) and Klebsiella pneumoniae (ATCC 4352). Three batches (ACE-2013-00092237, ACE-2013-00092238, and ACE-2013-00091756) of the product, SOLEVA SOLUTION, were tested at two concentrations (5400ppm and 1100ppm), on the day of production and at 48 hours after production of the product, using the ASTM E 1153 and ASTM E 1054 methods. The bacterial strains were transplanted on Nutrient broth for three consecutive times (stock culture used in any case should not be more than five passages) and incubated the first and second passages at 37°C ±1°C for 24 hours while the third was incubated at 37°C ± 1°C for 48 hours. The last preparation was referred to as the working culture. Fetal calf serum was added to each inoculum to achieve a 5% organic soil load. Five sterile glass carriers per product lot per organism were inoculated with 0.02 ml of suspension of the test organism. The inoculum was spread to within 3 mm of the edges of the carrier. The carriers were dried at 37°C ±1°C for 35 minutes. Each carrier was transferred to a sterile jar and was exposed to 5.0 ml of the use solution at 22°C ±2°C for 5 minutes. After the contact time the test mixture was vigorously stirred (for about 30 seconds before the end of the contact time) and 1.0ml and 0.1 ml were filtered twice; 20 ml of neutralizer were added to each filter unit and after filtration the membrane was aseptically transferred on agar plate and incubated at 37°C ±1°C for 48 hours and the number of colony forming units/plate was recorded; the geometric mean of the number of the bacteria surviving on the five test carriers was calculated multiplying per the neutralizer volume plus test item volume (i.e. 25 ml). Controls included those for carrier quantitation, inoculum count, viability, neutralization confirmation, sterility, and water. The reported average colony forming units (CFU) per control carrier, for each test microorganism, are as follows: *Klebsiella pneumoniae* 3.6 x 10<sup>6</sup>, *Staphylococcus aureus* 3.9 x 10<sup>6</sup>.

11. MRID 495733-19 "EVALUATION OF THE AVAILABLE CHLORINE AS GERMICIDAL EQUIVALENT CONCENTRATION AGAINST S. aureus ON GISELLE AND SOLEVA SOLUTIONS," Test Organism: Staphylococcus aureus (ATCC 6538), by Laura Brambilla. Study conducted at Eurofins Biolab S.R.L. Study completion date –December 24, 2012. Report No. 2012/1687 AMi.

This study was conducted against Staphylococcus aureus (ATCC 6538). Six batches (10-Oct-2012 h09:18, 10-Oct-2012 h09:47, 10-Oct-2012 h09:31, 10-Oct-2012, h09:57, 08-Oct-2012 h15:26, 08-Oct-2012 h15:47) of the product at two concentrations (5400 ppm of Cl<sub>2</sub> and 1100 ppm of Cl<sub>2</sub>), SOLEVA SOLUTIONS, were tested at or below the lower concentration limit using the AOAC Official Method 955.16. Sodium hypochlorite (NaOCI) was used as the data control standard at four concentrations, 5400, 1100, 200, and 50 ppm available Cl<sub>2</sub>. Letheen Broth was used as neutralizer, TSA was used as agar plate medium and 0.05 ml of 5% of fetal calf serum was the soil load. A 10ml aliquot of each test item, each batch and each dilution of NaClO standard solution were prepared and inoculated with 0.05ml of the bacterial test culture and placed in water bath of 20°C. After one minute of contact time, a subculture was prepared by transferring one loopful of each medicated mixture into a 10ml of Leethen Broth. After 1.5 minutes another 0.05ml of the bacterial test culture were added in each tube, shaken and returned in the bath. After additional 1 minute interval (2.5 minutes in test) a subculture tube was prepared in the same way. This operation was repeated to give total of 10 added increments so a total time of 14.5 minutes for each solution and addition of 0.5 ml total bacterial culture were required. The neutralized subcultures were incubated at 36-38°C for 48 hours and examined for macroscopic evidence of microbial growth. Controls included neutralization, viability control, purity, initial suspension population and sterility. The reported colony forming units per carrier is Staphylococcus aureus 9.5 x 107

12. MRID 495733-20 "EVALUATION OF SANITIZING BACTERICIDAL EFFICACY AGAINST S. aureus and K. pneumoniae FOR NON-FOOD HARD NON-POROUS SURFACES ON GISELLE AND SOLEVA SOLUTIONS," Test Organisms: Staphylococcus aureus (ATCC 6538) and Klebsiella pneumoniae (ATCC 4352), by Laura Brambilla. Study conducted at Eurofins Biolab S.R.L. Study completion date – September 26, 2013. Report No. S-2013-02010 AMi.

This study was conducted against *Staphylococcus aureus* (ATCC 6538) and *Klebsiella pneumoniae* (ATCC 4352). Three batches (ACE-2013-00092237, ACE-2013-00092238, and ACE-2013-00091756) of the product, SOLEVA SOLUTION, were tested at 500ppm FAC, on the day of production and at 48 hours after production of the product, using the ASTM E 1153 and ASTM E 1054 methods. The bacterial strains were transplanted on Nutrient broth for three consecutive times (stock culture used in any case should not be more than five passages) and incubated the first and second passages at 37°C ±1°C for 24 hours while the third was incubated at 37°C ± 1°C for 48 hours. The last preparation was referred to as the working culture. A use solution of 500 ppm was prepared by adding tap water. Fetal calf serum was added to each inoculum to achieve a 5% organic soil load. Five sterile glass carriers per product lot per organism were inoculated with 0.02 ml of suspension of the test organism. The inoculum was spread to

within 3 mm of the edges of the carrier. The carriers were dried at  $37^{\circ}\text{C} \pm 1^{\circ}\text{C}$  for 35 minutes. Each carrier was transferred to a sterile jar and was exposed to 5.0 ml of the use solution at  $22^{\circ}\text{C} \pm 2^{\circ}\text{C}$  for 5 minutes. After the contact time the test mixture was vigorously stirred (for about 30 seconds before the end of the contact time) and 1.0ml and 0.1 ml were filtered twice; 20 ml of neutralizer were added to each filter unit and after filtration the membrane was aseptically transferred on agar plate and incubated at  $37^{\circ}\text{C} \pm 1^{\circ}\text{C}$  for 48 hours and the number of colony forming units/plate was recorded; the geometric mean of the number of the bacteria surviving on the five test carriers was calculated multiplying per the neutralizer volume plus test item volume (i.e. 25 ml). Controls included those for carrier quantitation, inoculum count, viability, neutralization confirmation, sterility, and water. The reported average colony forming units (CFU) per control carrier, for each test microorganism, are as follows: *Klebsiella pneumoniae* 6.67 x  $10^6$ , *Staphylococcus aureus* 2.17 x  $10^7$ .

13. MRID 495733-21 "EVALUATION OF SANITIZING BACTERICIDAL EFFICACY FOR NON-FOOD AND FOOD HARD NON-POROUS SURFACES ON GISELLE AND SOLEVA SOLUTIONS," Test Organisms: *Staphylococcus aureus* (ATCC 6538) and *Klebsiella pneumoniae* (ATCC 4352), by Laura Brambilla. Study conducted at Eurofins Biolab S.R.L. Study completion date –November 18, 2013. Report No. S-2013-02191 AMi.

This study was conducted against Staphylococcus aureus (ATCC 6538) and Klebsiella pneumoniae (ATCC 4352). Three batches (ACE-2013-00099077, ACE-2013-00099078, and ACE-2013-00099076) of the product, SOLEVA SOLUTIONS, were tested were tested at 500ppm FAC, on the day of production and at 48 hours after production of the product, using the ASTM E 1153 and ASTM E 1054 methods. The bacterial strains were transplanted on Nutrient broth for three consecutive times (stock culture used in any case should not be more than five passages) and incubated the first and second passages at 36°-38°C for 24 hours while the third was incubated at 36°-38°C for 48 hours. The last preparation was referred to as the working culture. A use solution of 500 ppm was prepared by adding tap water. Fetal calf serum was added to each inoculum to achieve a 5% organic soil load. Five sterile glass carriers per product lot per organism were inoculated with 0.02 ml of suspension of the test organism. The inoculum was spread to within 3 mm of the edges of the carrier. The carriers were dried at 36-38°C for 35 minutes. Each carrier was transferred to a sterile jar and was exposed to 5.0 ml of the use solution at 20-24°C for 2 minutes. After the contact time the test mixture was vigorously stirred (for about 30 seconds before the end of the contact time) and 1.0 ml and 0.1 ml were filtered twice; 20 ml of neutralizer were added to each filter unit and after filtration the membrane was aseptically transferred on agar plate and incubated at 36°-38°C for 48 hours and the number of colony forming units/plate was recorded; the geometric mean of the number of the bacteria surviving on the five test carriers was calculated multiplying per the neutralizer volume plus test item volume (i.e. 25 ml). Controls included those for carrier quantitation, inoculum count, viability, neutralization confirmation, sterility, and water. The reported average colony forming units (CFU) per control carrier, for each test microorganism, are as follows: Klebsiella pneumoniae 11.3 x 106, Staphylococcus aureus  $5.1 \times 10^6$ 

14. MRID 495733-22 "EVALUATION OF THE AVAILABLE CHLORINE AS GERMICIDAL EQUIVALENT CONCENTRATION AGAINST S. aureus ON GISELLE AND SOLEVA SOLUTIONS," Test Organism: Staphylococcus aureus (ATCC 6538), by Laura Brambilla. Study conducted at Eurofins Biolab S.R.L. Study completion date –November 18, 2013. Report No. S-2013-02011 AMi.

This study was conducted against Staphylococcus aureus (ATCC 6538). Three batches (ACE-2013-00097292, ACE-2013-00097293, and ACE-2013-00097294) of the product, SOLEVA SOLUTIONS, were tested at or below the lower concentration limit using the AOAC Official Method 955.16. Sodium hypochlorite (NaOCI) was used as the data control standard at four concentrations, 500, 200, 100 and 50 ppm available Cl<sub>2</sub>. Letheen Broth was used as neutralizer, TSA was used as agar plate medium and 0.05 ml of 5% of fetal calf serum was the soil load. A 10ml aliquot of each test item (500 ppm), each batch and each dilution of NaClO standard solution were prepared and inoculated with 0.05ml of the bacterial test culture and placed in water bath of 20°C. After one minute of contact time, a subculture was prepared by transferring one loopful of each medicated mixture into a 10ml of Leethen Broth. After 1.5 minutes another 0.05ml of the bacterial test culture were added in each tube, shaken and returned in the bath. After additional 1 minute interval (2.5 minutes in test) a subculture tube was prepared in the same way. This operation was repeated to give total of 10 added increments so a total time of 14.5 minutes for each solution and addition of 0.5 ml total bacterial culture were required. The neutralized subcultures were incubated at 36-38°C for 48 hours and examined for macroscopic evidence of microbial growth. Controls included neutralization, viability control, purity, initial suspension population and sterility. The reported colony forming units per units per plate is Staphylococcus aureus 9.0 x 107

15. MRID 495733-23 "EVALUATION OF SANITIZING BACTERICIDAL EFFICACY AGAINST S. aureus AND K. pneumoniae FOR NON-FOOD AND FOOD HARD NON-POROUS SURFACES ON GISELLE AND SOLEVA SOLUTIONS," Test Organisms: Staphylococcus aureus (ATCC 6538) and Klebsiella pneumoniae (ATCC 4352), by Laura Brambilla. Study conducted at Eurofins Biolab S.R.L. Study completion date – August 7, 2014. Report No. S-2014-01594 AMi.

This study was conducted against Staphylococcus aureus (ATCC 6538) and Klebsiella pneumoniae (ATCC 4352). One batch (ACE-2014-00087806) of the product, SOLEVA SOLUTIONS, were tested at 440ppm FAC using the ASTM E 1153 method. The bacterial strains were transplanted on Nutrient broth for three consecutive times (stock culture used in any case should not be more than five passages) and incubated the first and second passages at 36°-38°C for 24 hours while the third was incubated at 36°-38°C for 48 hours. The last preparation was referred to as the working culture. A use solution of 440 ppm was prepared by adding tap water. Fetal calf serum was added to each inoculum to achieve a 5% organic soil load. Five sterile glass carriers per product lot per organism were inoculated with 0.02 ml of suspension of the test organism. The inoculum was spread to within 3 mm of the edges of the carrier. The carriers were dried at 36-38°C for 35 minutes. Each carrier was transferred to a sterile jar and was exposed to 5.0 ml of the use solution at 20-24°C for 2 minutes. After the contact time the test mixture was vigorously stirred (for about 30 seconds before the end of the contact time) and 1.0 ml and 0.1 ml were filtered twice; 20 ml of neutralizer were added to each filter unit and after filtration the membrane was aseptically transferred on agar plate and incubated at 36°-38°C for 48 hours and the number of colony forming units/plate was recorded; the geometric mean of the number of the bacteria surviving on the five test carriers was calculated multiplying per the neutralizer volume plus test item volume (i.e. 25 ml). Controls included those for carrier quantitation, inoculum count, viability, neutralization confirmation, sterility, and water. The reported average colony forming units (CFU) per control carrier, for each test microorganism, are as follows: Klebsiella pneumoniae 1.2 x 10<sup>7</sup>, Staphylococcus aureus 1.9 x 10<sup>7</sup>.

16. MRID 495733-24 "EVALUATION OF THE AVAILABLE CHLORINE AS GERMICIDAL EQUIVALENT CONCENTRATION AGAINST S. aureus ON GISELLE

AND SOLEVA SOLUTIONS," Test Organism: Staphylococcus aureus (ATCC 6538), by Laura Brambilla. Study conducted at Eurofins Biolab S.R.L. Study completion date –August 08, 2014. Report No. S-2013-01595 AMi.

This study was conducted against Staphylococcus aureus (ATCC 6538). One batch (ACE-2014-00085605) of the product. SOLEVA SOLUTIONS, were tested at or below the lower concentration limit using the AOAC Official Method 955.16. Sodium hypochlorite (NaOCI) was used as the data control standard at four concentrations, 440, 200, 100 and 50 ppm available Cl<sub>2</sub>. Letheen Broth was used as neutralizer, TSA was used as agar plate medium and 0.05 ml of 5% of fetal calf serum was the soil load. A 10ml aliquot of each test item (440 ppm), each batch and each dilution of NaCIO standard solution were prepared and inoculated with 0.05ml of the bacterial test culture and placed in water bath of 20°C. After one minute of contact time, a subculture was prepared by transferring one loopful of each medicated mixture into a 10ml of Leethen Broth. After 1.5 minutes another 0.05ml of the bacterial test culture were added in each tube, shaken and returned in the bath. After additional 1 minute interval (2.5 minutes in test) a subculture tube was prepared in the same way. This operation was repeated to give total of 10 added increments so a total time of 14.5 minutes for each solution and addition of 0.5 ml total bacterial culture were required. The neutralized subcultures were incubated at 36-38°C for 48 hours and examined for macroscopic evidence of microbial growth. Controls included neutralization, viability control, purity, initial suspension population and sterility. The reported colony forming units per carrier is Staphylococcus aureus 2.05 x 108

## V. RESULTS

MRID#	Organism	Lot Number	Average Log <sub>10</sub> /carrier		Log
			Test	Control	reduction
495733-09	Clostridium difficile (spore	BATCH 16-Jan- 2014 h10:42	1.28	7.30	>6.02
	form) (ATCC 43598)	BATCH 27-Jan- 2014 h10:30	0.96	7.00	>6.34

MRID	Organism	Batch No.	Results (pg/ml HIV-1 p24)		Log
Number			Test	Dried Virus Control	Reduction
495733-11	Human Immunodeficiency	Batch 27-Jan- 2014h09:50	1.36 ( <lod)* 0.267 (<lod)*< td=""><td>1000</td><td>&gt;99.9</td></lod)*<></lod)* 	1000	>99.9
	Virus (HIV-1)	Batch 27-Jan- 2014 h10:02	1.633 ( <lod)* &lt;0.000</lod)* 		>99.9

<sup>\* &</sup>lt;LOD = lower than the Limit of Detection of the test virus

MRID Number	Organism	Lot#	Contact Time	Growth/ Total Tested	Dried Carrier Count (CFU/carrier)
	Trichophyton	10/15/13 h08:37	5 minutes	0/10	- a 404
495733-12	mentagrophytes	10/15/13 h0849	(No Soil)	0/10	Count
		14-NOV-2012 h11:20 (Solution at 6625 ppm of Cl <sub>2</sub> ) T0	5 minutes (Soil)	3/10	1.5 x 10 <sup>4</sup>
		14-NOV-2012 h12:00 (Solution at 6625 ppm of Cl <sub>2</sub> ) T0	5 minutes (Soil)	3/10	
495733-14	Trichophyton mentagrophytes	29-N0V-20I2 h10:13 (Solution at 6625 ppm of Cl <sub>2</sub> ) T0	5 minutes (No Soil)	0/10	1.2 x 10 <sup>4</sup>
		29-N0V-2012 h10:24 (Solution at 6625 ppm of Cl <sub>2</sub> ) T0	5 minutes (No Soil)	0/10	
		21-Dec-2012 h10:59 (Solution at 5400 ppm of Cl <sub>2</sub> ) T0	5 minutes (No Soil)	0/10	1.9 x 10 <sup>4</sup>
		21-Dec-2012 h11:25 (Solution at 5400 ppm of Cl <sub>2</sub> ) T0	5 minutes (No Soil)	0/10	

MRID#	Organism	Test/Control	Concentration			Sı	ibcu	ltur	e N	umb	er			
		Substance	or Lot	1	1 2 3 4			5	6	7	8	9	10	
			50 ppm	0	+	+	+	+	+	+	+	+	+	
		NaOCI	200 ppm	0	0	0	0	+	+	+	+	+	+	
		Control	1100 ppm	0	0	0	0	0	0	0	0	0	+	
	Part I have		5400ppm	0	0	0	0	0	0	0	0	0	0	
		10/10/12	50 ppm	0	0	0	0	0	0	+	+	+	+	
		h09:18	200 ppm	0	0	0	0	0	0	0	0	0	+	
		(5400ppm)	5400 ppm	0	0	0	0	0	0	0	0	0	0	
		10/10/12	50 ppm	0	0	0	0	0	+	+	+	+	+	
		h09:47	200 ppm	0	0	0	0	0	0	0	0	0	+	
	Course	(1100ppm)	1100 ppm	0	0	0	0	0	0	0	0	0	0	
495733-19	S. aureus (ATCC	10/10/12	50 ppm	0	0	0	0	0	+	+	+	+	+	
495733-19	6538)	h09:31	200 ppm	0	0	0	0	0	0	0	0	0	+	
	0330)	(5400ppm)	5400 ppm	0	0	0	0	0	0	0	0	0	0	
		10/10/12	50 ppm	0	0	0	0	0	+	+	+	+	+	
		h09:57	200 ppm	0	0	0	0	0	0	0	0	0	+	
		(1100ppm)	1100 ppm	0	0	0	0	0	0	0	0	0	0	
		10/08/12	50 ppm	0	0	0	0	0	+	+	+	+	+	
		h15:26	200 ppm	0	0	0	0	0	0	0	0	0	+	
		(5400ppm)	5400 ppm	0	0	0	0	0	0	0	0	0	0	
		10/08/12	50 ppm	0	0	+	+	+	+	+	+	+	+	
		h15:47 200 ppm 0	0	0	0	0	0	0	0	+	+			
	T. Control	(1100ppm)	1100 ppm	0	0	0	0	0	0	0	0	0	+	
	The State of			50 ppm	0	0	0	0	+	+	+	+	+	+
		NaOCI	100 ppm	0	0	0	0	0	+	+	+	+	+	
		Control	200 ppm	0	0	0	0	0	0	0	0	+	+	
			500 ppm	0	0	0	0	0	0	0	0	0	0	
			50 ppm	0	0	0	+	+	+	+	+	+	+	
		ACE-2013-	100 ppm	0	0	0	0	+	+	+	+	+	+	
		00097292	200 ppm	0	0	0	0	0	0	+	+	+	+	
495733-22	S. aureus		500 ppm	0	0	0	0	0	0	0	0	0	0	
493733-22	(ATCC		50 ppm	0	0	0	+	+	+	+	+	+	+	
	6538)	ACE-2013-	100 ppm	0	0	0	0	0	0	+	+	+	+	
	0000)	00097293	200 ppm	0	0	0	0	0	0	0	+	+	+	
			500 ppm	0	0	0	0	0	0	0	0	0	0	
	13.00		50 ppm	0	0	0	+	+	+	+	+	+	+	
		ACE-2013-	100 ppm	0	0	0	+	+	+	+	+	+	+	
		00097294	200 ppm	0	0	0	0	0	0	0	0	0	+	
			500 ppm	0	0	0	0	0	0	0	0	0	0	
			50 ppm	0	0	0	0	+	+	+	+	+	+	
	S. aureus	NaOCI	100 ppm	0	0	0	0	0	0	+	+	+	+	
495733-24	(ATCC	Control	200 ppm	0	0	0	0	0	0	0	+	+	+	
	6538)		440 ppm	0	0	0	0	0	0	0	0	0	0	
		ACE-2014- 00085605	440 ppm	0	0	0	0	0	0	0	0	0	0	

MRID	Organism	Batch No.		Dried Virus			
Number			10 <sup>-1</sup> dilution	10 <sup>-2</sup> to 10 <sup>-10</sup> dilutions	TCID <sub>50</sub> / 0.1 ml	Log Reduction	Control (TCID <sub>50</sub> /0.1ml)
	H09:15 (5400ppm)	Complete Inactivation	Complete Inactivation	≤10 <sup>0.50</sup>	≥4.88		
		H09:30 (5400ppm)	Complete Inactivation	Complete Inactivation	≤10 <sup>0.50</sup>	≥4.88	4.05.20
495733-	D-lii	H09:45 (1100ppm)	Complete Inactivation	Complete Inactivation	≤10 <sup>0.50</sup>	≥4.88	10 <sup>5.38</sup>
15	Poliovirus	H09:55 (1100ppm)	Complete Inactivation	Complete Inactivation	≤10 <sup>0.50</sup>	≥4.88	
		H09:15 (5400ppm) T48	Complete Inactivation	Complete Inactivation	≤10 <sup>0.50</sup>	≥4.63	10 <sup>5.13</sup>
			Complete Inactivation	Complete Inactivation	≤10 <sup>0.50</sup>	≥4.63	
		H10:15 (5400ppm)	Cytotoxicity	Complete Inactivation	≤10 <sup>1.50</sup>	≥4.38	
495733-		H10:30 (5400ppm)	Cytotoxicity	Complete Inactivation	≤10 <sup>1.50</sup>	≥4.38	
16	Feline Calicivirus	H10:45 (1100ppm)	Complete Inactivation	Complete Inactivation	≤10 <sup>0.50</sup>	≥5.38	10 <sup>5.88</sup>
		H10:55 (1100ppm)	Complete Inactivation	Complete Inactivation	≤10 <sup>0.50</sup>	≥5.38	
		H10:15 (5400ppm) T48	Cytotoxicity	Complete Inactivation	≤10 <sup>1.50</sup>	≥4.25	10 <sup>5.75</sup>
		H10:45 (1100ppm) T48	Complete Inactivation	Complete Inactivation	≤10 <sup>0.50</sup>	≥5.25	
		H09:18 (5400ppm)	Cytotoxicity	Complete Inactivation	≤10 <sup>1.50</sup>	≥4.38	
	Bovine viral	H09:47 (5400ppm)	Cytotoxicity	Complete Inactivation	≤10 <sup>1.50</sup>	≥4.38	
495733- 17	virus	diarrhea virus H09:31 Cytotoxicity Complete	Complete Inactivation	≤10 <sup>1.50</sup>	≥4.38	10 <sup>5.88</sup>	
	ATCC VR- 534	H09:57 (1100ppm)	Cytotoxicity	Complete Inactivation	≤10 <sup>1.50</sup>	≥4.38	
		H09:18 (5400ppm) T48	Cytotoxicity	Complete Inactivation	≤10 <sup>1.50</sup>	≥4.63	10 <sup>5.13</sup>
		H09:47 (1100ppm) T48	Cytotoxicity	Complete Inactivation	≤10 <sup>1.50</sup>	≥4.63	

MRID Number	Contact Time	Batch #	No. Exhibit	ting Growth/Tota	al No. Tested			
Number	Time		S. aureus	S. choleraesuis	P. aeruginosa			
		ACE-2013-00108210 (5700ppm)	1/60	0/60	1/60			
495733-10	10 minutes	ACE-2013-00108251 (5700ppm)	1/60	0/60	0/60			
		ACE-2013-00108252 (5700ppm)	0/60	0/60	0/60			
		Inoculum Count (CFU/carrier)	4.0x10 <sup>7</sup>	3.7x10 <sup>7</sup>	2.3x10 <sup>7</sup>			
AS INCH		26-Sep-2012 h10:23 (5400ppm)	26/60	5/60	2/60			
		26-Sep-2012 h10:50 (1100ppm)	36/60	8/60	3/60			
		27-Sep-2012 h11:10 (5400ppm)	19/60	5/60	3/60			
		27-Sep-2012 h11:20 (1100ppm)	44/60	9/60	12/60			
		02-Oct-2012 h09:26 (5400ppm)	6/60	10/60	2/60			
		02-Oct-2012 h09:49 (1100ppm)	21/60	14/60	4/60			
		Amendment #1						
495733-13	10 minutes	11-Oct-2012 h11:00 (5400 ppm) (w/o FCS 5%)	1/60	N/A	N/A			
495733-13		11-Oct-2012 h11:20 (6625 ppm) (w/o FCS 5%)	1/60	N/A	N/A			
		Amendment #2						
		30-Oct-2012 h10:25 (6625ppm)	1/60	1/60	1/60			
		31-Oct-2012 h09:10 (6625ppm)	1/60	1/60	0/60			
		31-Oct-2012 h09:34 (6625ppm)	0/60	0/60	0/60			
		Inoculum Count (CFU/carrier)						
		5400 ppm	3.5x10 <sup>7</sup>	8.27x10 <sup>7</sup>	3.67x10 <sup>7</sup>			
		6625 ppm	2.9x10 <sup>7</sup>	6.2x10 <sup>7</sup>	2.9 x10 <sup>7</sup>			

MRID Number	Organism	Lot No.	CFU/Carrier Average Log <sub>10</sub>	Percent Reduction	Carrier Population (Log <sub>10</sub> CFU/Carrier)
	THE WAR	10/05/12 h09:15 (5400ppm)	<2.54	>99.99	
405700		10/05/12 h09:45 (1100ppm)	<2.54	2.54 >99.99	
495733-	S. aureus	10/05/12 h10:15 (5400ppm)	<2.54	>99.99	0.50
18	0. 44.040		<2.54	>99.99	6.59
(5 minutes)		10/03/12 h13:50 (5400ppm)	<2.54	>99.99	
		10/03/12 h14:10 (1100ppm)	<2.54	>99.99	
		10/05/12 h09:15 (5400ppm)	<2.54	>99.99	6.56

		10/05/12 h09:45 (1100ppm)	<2.54	>99.99	
	К.	10/05/12 h10:15 (5400ppm)	<2.54	>99.99	
		10/05/12 h10:45 (1100ppm)	<2.54	>99.99	
	pneumonia	10/03/12 h13:50 (5400ppm)	<2.54	>99.99	
		10/03/12 h14:10 (1100ppm)	<2.54	>99.99	
		ACE-2013-00092237 (500ppm)	<2.54	100.00	
495733-	S. aureus	ACE-2013-00092238 (500ppm)	<2.54	100.00	7.33
20		ACE-2013-00091756 (500ppm)	<2.54	100.00	
(5	K.	ACE-2013-00092237 (500ppm)	<2.54	100.00	
minutes)		ACE-2013-00092238 (500ppm)	<2.54	100.00	6.76
	pneumonia	ACE-2013-00091756 (500ppm)	<2.54	100.00	
	S. aureus	ACE-2013-00099077 (500ppm)	<2.54	100.00	
495733-		ACE-2013-00099078 (500ppm)	<2.54	>99.99	6.75
21		ACE-2013-00099076 (500ppm)	<2.54	>99.99	
(2		ACE-2013-00099077 (500ppm)	<2.54	100.00	
minutes)	K.	ACE-2013-00099078 (500ppm)	2.57	>99.99	6.98
	pneumonia	ACE-2013-00099076 (500ppm)	<2.54	100.00	
495733- 23	S. aureus	AOF 0044 00007000 (440	<2.54	100.00	7.28
	K. pneumonia	ACE-2014-00087806 (440ppm)	<2.54	100.00	7.09

#### III. CONCLUSION

1. The submitted efficacy data **support** the use of the product, SOLEVA™ SOLUTION, as a disinfectant with against the following microorganisms on **pre-cleaned** hard, nonporous surfaces for a 10 minutes contact time:

MRID 495733-09 Clostridium difficile (spore form) (ATCC 43598) at 5700ppm FAC MRID 495733-12 and 14 Trichophyton mentagrophytes at 5400ppm FAC

2. The submitted efficacy data **support** the use of the product, SOLEVA™ SOLUTION, as a disinfectant against the following microorganisms on hard, nonporous surfaces in the presence of a 5% organic soil load, for a 10 minutes contact time:

MRID 495/33-10 and	3 Staphylococcus aureus (ATCC 6538) at 5700ppm FAC
MRID 495733-10 and	3 Salmonella choleraesuis (ATCC 10708) at 5700ppm FAC
MRID 495733-10 and	3 Pseudomonas aeruginosa (ATCC 15442) at 5700ppm FAC
MRID 495733-10	luman Immunodeficiency Virus (HIV-1) at 5700ppm FAC
MRID 495733-15	Poliovirus type 1 LSc-2ab (Sabin) at 5400ppm and 1100ppm FAC
MRID 495733-16	eline calicivirus (Strain F-9 (FCV); ATCC VR-782) surrogate for Human
	lorovirus at 5400ppm and 1100ppm FAC
MRID 495733-17	Bovine viral diarrhea virus ATCC VR-534 at 5400ppm and 1100ppm AC

3. The submitted efficacy data **support** the use of the product, SOLEVA™ SOLUTION, as a sanitizer against the following microorganisms on hard, nonporous surfaces in the presence of a 5% organic soil load:

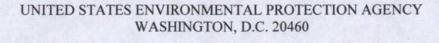
MRID 495733-18	Staphylococcus aureus (ATCC 6538) and Klebsiella pneumoniae (ATCC
	4352) at 5400ppm and 1100ppm FAC in 5 minutes
MRID 495733-20	Staphylococcus aureus (ATCC 6538) and Klebsiella pneumoniae (ATCC
	4352) at 500ppm FAC in 5 minutes
MRID 495733-21	Staphylococcus aureus (ATCC 6538) and Klebsiella pneumoniae (ATCC
	4352) at 500ppm FAC in 2 minutes
MRID 495733-23	Staphylococcus aureus (ATCC 6538) and Klebsiella pneumoniae (ATCC
	4352) at 440ppm FAC in 2 minutes

# IV. LABEL

- 1. While it is mandatory to pre-clean visibly (heavily) soiled surfaces, pre-cleaning is systematic for all surfaces (visibly clean and soiled) for disinfection claims for fungi and *Clostridium difficile* spores. Registrant must <u>change</u>:
  - "To kill fungi or Clostridium difficile spores, pre-clean a heavily soiled surface according to
    the instructions below prior to spraying SOLEVA 0.6% solution" to read "To kill fungi or
    Clostridium difficile spores, pre-clean surfaces according to the instructions below
    prior to spraying SOLEVA 0.6% solution".
  - "Special Cleaning Instructions Prior to Disinfection of Heavily Soiled Surfaces or for Clostridium difficile spores" to read "Special Pre-Cleaning Instructions Prior to Disinfection for Fungi and Clostridium difficile spores – Cleaning Instructions Prior to Disinfection of Heavily Soiled Surfaces or for Clostridium difficile spores"
- 2. The proposed label claims **are acceptable** regarding the use of the product, Salt Cartridge for Giselle® in the production (the generation) of SOLEVA™ Solution 0.05% (SOLEVA 0.05%) using Giselle, as a sanitizer spray against Staphylococcus aureus ATCC 6538 and Klebsiella pneumonia ATCC 4352 in the presence of 5% organic soil (blood serum), on hard, nonporous surfaces, when used undiluted, at room temperature, for 2 minutes contact time. These claims **are supported** by the applicant's data.
- 3. The proposed label claims are acceptable regarding the use of the product, Salt Cartridge for Giselle® in the production (the generation) of SOLEVA™ Solution 0.1% (SOLEVA 0.1%) using Giselle, as a sanitizer spray against Staphylococcus aureus ATCC 6538 and Klebsiella pneumonia ATCC 4352 in the presence of 5% organic soil (blood serum), on hard, nonporous surfaces, when used undiluted, at room temperature, for 2 minutes contact time. These claims are supported by the applicant's data.
- 3. The proposed label claims **are acceptable** regarding the use of the product, Salt Cartridge for Giselle® in the production (the generation) of SOLEVA™ Solution 0.6% (SOLEVA 0.6%) using Giselle, as a disinfectant spray against *Staphylococcus aureus* ATCC 6538, Pseudomonas aeruginosa ATCC 15442, Salmonella enterica ATCC 10708, Poliovirus type 1 Sabin Strain Lcs2b, Feline Calicivirus F-9 ATCC V'R782, and Hepatitis C virus ATCC VR534, HIV-1 (HTLV IIIB), in

the presence of 5% organic soil (blood serum), on hard, nonporous surfaces, when used undiluted, at room temperature, for 10 minutes contact time. These claims **are supported** by the applicant's data.

4. The proposed label claims **are acceptable** regarding the use of the product, Salt Cartridge for Giselle<sup>®</sup> in the production (the generation) of SOLEVA™ Solution 0.6% (SOLEVA 0.6%) using Giselle, as a disinfectant spray against *Trichophyton mentagrophytes* ATCC 9533 and *Clostridium difficile* ATCC 43598, on **pre-cleaned** hard, nonporous surfaces, when used undiluted, at room temperature, for 10 minutes contact time. These claims **are supported** by the applicant's data.





OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

July 30, 2015

# **MEMORANDUM**

Subject:

Acute Toxicity Review for EPA File Symbol 91386-R

Data Package 426356 Product Name: Giselle®

From:

Wallace Powell, Biologist

Chemistry and Toxicology Team

Product Science Branch

Antimicrobials Division (7510P)

Through:

Karen Hicks, Team Leader

Chemistry and Toxicology Team

Product Science Branch

Antimicrobials Division (7510P)

To:

Demson Fuller, PM 32/ Wanda Henson

Regulatory Management Branch II Antimicrobials Division (7510P)

Applicant: Industrie De Nora, S.p.A.

FORMULATION FROM PROPOSED LABEL:

Active Ingredient: Sodium chloride (EPA PC Code 013905)

Other Ingredient(s):

Total:

% by weight 99.86

Im Black mell for KPH

0.14

100.0

## BACKGROUND

In support of the product acute toxicity data requirements for registration of the subject product, Giselle®, the applicant is using the cite-all method. The Giselle® machine converts sodium chloride to produce ready-to-use sodium hypochlorite solution of 0.05, 0.1, or 0.6 percent concentration. The pesticide product will be the registered sodium chloride precursor; the resultant sodium hypochlorite solution will not be sold or distributed in commerce. Product Science Branch (PSB) has been informed that the applicant is using the cite-all method to support the sodium chloride entity rather than the sodium hypochlorite. PSB has been asked to determine the precautionary labeling for the sodium chloride product.

# RECOMMENDATION

Based on a substantially similar registered sodium chloride product, the acute Toxicity Categories for Giselle® (as sodium chloride technical grade) are those listed in the table below.

# Summary

The acute toxicity profile of Giselle® is currently:

Study	Method of Support	Toxicity Category	Status
Acute Oral Toxicity			
Acute Dermal Toxicity			
Acute Inhalation Toxicity	0'411	III	A
Primary Eye Irritation	Cite-all		Acceptable
Primary Dermal Irritation			
Dermal Sensitization		Non-sensitizer	

# **Product Labeling**

The Agency's *Label Review Manual* (www.epa.gov/oppfead1/labeling/lrm/) indicates the following for Giselle<sup>®</sup>, to be placed under the PRECAUTIONARY STATEMENTS heading:

#### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Harmful if swallowed, absorbed through skin, or inhaled. Causes moderate eye irritation. Avoid contact with eyes, skin, or clothing. Avoid breathing vapor or spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

The First Aid statements in the submitted labeling for the hypochlorite (dated February 13, 2015, and containing *If in eyes*, *If on skin*, and *If swallowed* First Aid instructions) would be acceptable for the sodium chloride product with one exception: *If inhaled* instructions should be added:

#### If inhaled:

- · Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.
- Call a poison control center or doctor for further treatment advice.

# 21-Day Screen Completed by Contractor

21-Day Expires on 3-11-15

Jacket # 9/386 - R MRID# 495733

Content Screen: Recommend to Pass/Fail

11-3 Review: Pass/Fail/NA

Overall Status: Recommend to Pass/Fail

Transfer This Jacket to:

DEMSON FULCER

# Henson, Wanda

From:

Eronini, Lynette

Sent:

Friday, July 31, 2015 7:24 PM

To:

Henson, Wanda

Subject: Attachments: 91386-R\_D426355\_Salt Cartridge for Giselle DRAFT Product Chemistry Review 91386-R\_D426355\_Salt Cartridge for Giselle DRAFT Product Chemistry Review.doc

Here is the status of 91386-R\_D426355\_Salt Cartridge for Giselle.

The Basic CSF, February 13, 2015 is unacceptable. Group A Product Chemistry data requirements have been met, with the exception of the 830.1700 Preliminary Analysis 830.1800 Enforcement Analytical Method and 830.1900 Submittal of Samples guidelines as mentioned in #2 of the FINDINGS above. Group B Product Chemistry data requirements have not been met. The unmet data requirements are to be submitted to the agency.

Attached is draft of the chemistry review.

Lynette T. Umez-Eronini Antimicrobials Division Office of Pesticide Program 703-347-0132

**35** 

## Henson, Wanda

From: Sent: To: Sheryl Dolan <sdolan@actagroup.com> Tuesday, August 04, 2015 11:04 AM Fuller, Demson; Henson, Wanda

Subject:

De Nora

#### Wanda and Demson:

Please advise if there is more that we need to do to resolve the product chemistry issues that Wanda and I discussed late yesterday. I reviewed the submission after we spoke and note the following:

- The preliminary analysis clearly covers five (5) batches of the salt; I have no explanation for why the chemist is only finding three.
- The data matrix should resolve the physical-chemical properties "gaps".
- We would like to review with you the requested changes to the CSF; as discussed, the chemist appeared to be
  confusing an "inert" with an "impurity", at least insofar as the chemist was asking for the supplier of the impurity.

As the PRIA date is the end of next week, we clearly wish to do all we can to resolve these issues expeditiously.

Thank you,

#### SHERYL LINDROS DOLAN

# ACTA ASIA | EUROPE | THE AMERICAS

2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037 T: 202-266-5031 | F: 202-557-3836 | actagroup.com



#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

February 25, 2015

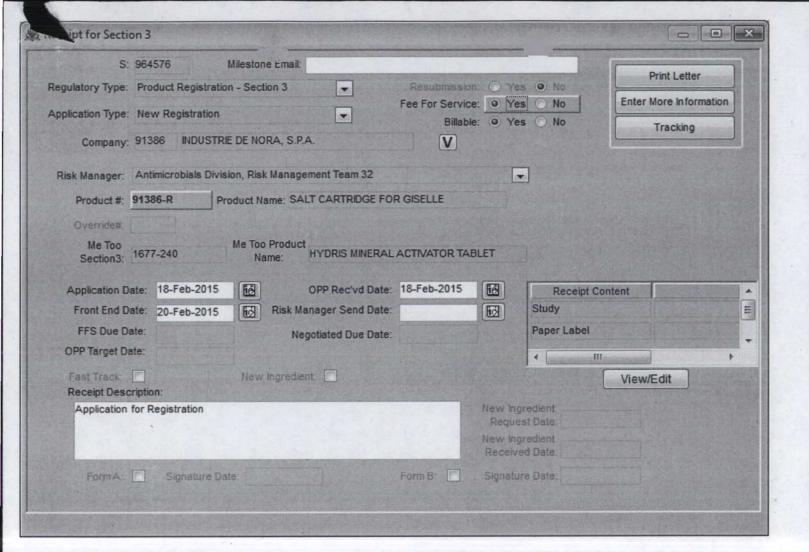
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

DE NORA TECH, INC. INDUSTRIE DE NORA, S.P.A. 7590 DISCOVERY LANE CONCORD, OH 44077

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 18-FEB-15. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.



#### Safety Data Sheet for Sodium Chloride

#### Safety Data Sheet Sodium chloride

#### Safety Data Sheet dated 3/11/2014, version 1

#### 1. IDENTIFICATION

Product identifier

Mixture identification:

Trade name: Salt Cartridge for Giselle® ( Sodium Chloride)

CAS number: 7647-14-5

Other means of identification:

EC number:

231-598-3

Recommended use of the chemical and restrictions on use

Recommended use: Salt for use with Giselle

Restrictions on use:

Any other use outside recommended

Name, address, and telephone number of the chemical manufacturer, importer, or other responsible party

Industrie De Nora s.p.a - Via Bistolfi 35 - 20134 Milano - Italy

Industrie De Nora s.p.a - Phone+39 02 21292830 Fax +39 02 21292831

Competent person responsible for the safety data sheet:

info@denoranext.com

Emergency phone number

CHEMTREC +1 800 424 9300

Industrie De Nora s.p.a c/o De Nora Tech - Phone +1 440 285 0361

#### 2. HAZARD(S) IDENTIFICATION

Classification of the chemical

The product is not classified as dangerous according to OSHA Hazard Communication Standard (29 CFR 1910.1200).

Label elements

Symbols:

None

Hazard statements:

None

Precautionary statements:

None

**Special Provisions:** 

None

Hazards not otherwise classified identified during the classification process:

None

Ingredient(s) with unknown acute toxicity:

None.

Additional classification information

NFPA rating:



HMIS rating:

DENORA\_NACL/1 Page n. 1 of 7

#### Safety Data Sheet Sodium chloride



#### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substances

Identification of the substance:

CAS number: 7647-14-5 EC number: 231-598-3

Mixtures

N.A.

#### 4. FIRST-AID MEASURES

Description of necessary measures

In case of skin contact:

Wash with plenty of water and soap.

In case of eyes contact

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

In case of Ingestion:

Do not under any circumstances induce vomiting. OBTAIN A MEDICAL EXAMINATION

IMMEDIATELY.

In case of Inhalation:

Remove casualty to fresh air and keep warm and at rest.

Most important symptoms/effects, acute and delayed

None

Indication of immediate medical attention and special treatment needed

Treatment

None

#### 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media:

Water.

Carbon dioxide (CO2).

Unsuitable extinguishing media:

None in particular.

Specific hazards arising from the chemical

Do not inhale explosion and combustion gases.

Burning produces heavy smoke.

Hazardous combustion products:

None

Explosive properties: N.A.
Oxidizing properties: N.A.

Special protective equipment and precautions for fire-fighters

Use suitable breathing apparatus.

Collect contaminated fire extinguishing water separately. This must not be discharged into

drains.

Move undamaged containers from immediate hazard area if it can be done safely.

DENORA\_NACL/1 Page n. 2 of 7

#### Safety Data Sheet Sodium chloride

#### 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment, and emergency procedures

Wear personal protection equipment.

Remove all sources of ignition.

Wear breathing apparatus if exposed to vapours/dusts/aerosols.

Provide adequate ventilation.

Remove persons to safety.

Use appropriate respiratory protection.

See protective measures under point 7 and 8.

Methods and materials for containment and cleaning up

Wash with plenty of water.

#### 7. HANDLING AND STORAGE

Precautions for safe handling

Avoid contact with skin and eyes, inhaltion of vapours and mists.

Do not use on extensive surface areas in premises where there are occupants.

Do not eat or drink while working.

See also section 8 for recommended protective equipment.

Conditions for safe storage, including any incompatibilities

Keep away from food, drink and feed.

Incompatible materials:

None in particular.

Instructions as regards storage premises:

Adequately ventilated premises.

Storage temperature:

Store at ambient temperature.

#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

No occupational exposure limit available

**DNEL Exposure Limit Values** 

N.A.

PNEC Exposure Limit Values

N.A

Appropriate engineering controls:

None

Individual protection measures

Eye protection:

Not needed for normal use. Anyway, operate according good working practices.

Protection for skin:

Use clothing that provides comprehensive protection to the skin, e.g. cotton, rubber, PVC or

viton.

Protection for hands:

Use protective gloves that provides comprehensive protection, e.g. P.V.C., neoprene or rubber.

Respiratory protection:

Not needed for normal use.

Thermal Hazards:

None

#### 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance and colour: solid Odour: None Odour threshold: N.A. pH: 7,0

Melting point / freezing point: 801 °C

Initial boiling point and boiling range: 1413 °C

Solid/gas flammability: N.

DENORA\_NACL/1 Page n. 3 of 7

#### Safety Data Sheet Sodium chloride

Upper/lower flammability or explosive limits: N.A.

N.A. Vapour density: N.A. ° F Flash point: Evaporation rate: N.A. Vapour pressure: N.A.

Relative density: 2.1650 g/cm3 Solubility in water: 358 g/L (20°C)

Solubility in oil: N.A.

Partition coefficient (n-octanol/water): N.A.

Auto-ignition temperature: N.A. Decomposition temperature: N.A. Viscosity: N.A. Miscibility: N.A. Fat Solubility: N.A. Conductivity: N.A.

Substance Groups relevant properties N.A.

#### 10. STABILITY AND REACTIVITY

Reactivity

Stable under normal conditions

Chemical stability

Stable under normal conditions

Possibility of hazardous reactions

None

Conditions to avoid

Stable under normal conditions.

Incompatible materials

None in particular.

Hazardous decomposition products

#### 11. TOXICOLOGICAL INFORMATION

Information on toxicological effects

Toxicological information of the substance:

Sodium chloride - CAS: 7647-14-5

a) acute toxicity:

Test: LD50 - Route: Oral - Species: Rat = 3000 mg/kg

Test: LD50 - Route: Skin - Species: Rabbit > 10000 mg/kg

Test: LC50 - Route: Inhalation - Species: Rat > 42000 mg/m3 - Duration: 1h

b) skin corrosion/irritation:

Test: Skin Irritant - Route: Skin - Species: Rabbit Negative - Notes: No or only very minor

irritation

c) serious eye damage/imitation:

Test: Eye Irritant - Species: Rabbit 100 mg - Notes: moderate irritation

Substance(s) listed on the NTP report on Carcinogens:

Substance(s) listed on the IARC Monographs:

Substance(s) listed as OSHA Carcinogen(s):

No.

Substance(s) listed as NIOSH Carcinogen(s):

No.

DENORA\_NACL/1 Page n. 4 of 7

#### Safety Data Sheet Sodium chloride

#### 12. ECOLOGICAL INFORMATION

**Ecotoxicity** 

Adopt good working practices, so that the product is not released into the environment.

Sodium chloride - CAS: 7647-14-5

a) Aquatic acute toxicity:

Endpoint: LC50 - Species: Fish > 1000 mg/l - Duration h: 96

Endpoint: LC50 - Species: Crustaceans > 736 mg/l - Duration h: 48

Endpoint: EC50 - Species: Crustaceans > 403 mg/l - Duration h: 48

Persistence and degradability

Bioaccumulative potential N.A.

Mobility in soil

N.A.

Other adverse effects

None

#### 13. DISPOSAL CONSIDERATIONS

Product or rinsates that cannot be used must be diluted with water before disposal in a sanitary sewer.

#### 14. TRANSPORT INFORMATION

**UN number** 

Not classified as dangerous in the meaning of transport regulations.

UN proper shipping name

NA

Transport hazard class(es)

N.A.

Packing group

NA

**Environmental hazards** 

ADR-Environmental Pollutant: No

IMDG-Marine pollutant: No Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)

N.A.

Special precautions

NA

#### 15. REGULATORY INFORMATION

**USA** - Federal regulations

TSCA - Toxic Substances Control Act

This substance is listed on the TSCA inventory.

TSCA listed substances:

SARA - Superfund Amendments and Reauthorization Act

Section 302 - Extremely Hazardous Substances: No.

Section 304 - Hazardous substances: No. Section 313 - Toxic chemical list: No.

CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act

No substances listed.

CAA - Clean Air Act

CAA listed substances:

None.

CWA - Clean Water Act

CWA listed substances:

None.

USA - State specific regulations

DENORA\_NACL/1 Page n. 5 of 7

#### Safety Data Sheet Sodium chloride

California Proposition 65

Substance(s) listed under California Proposition 65:

None

Massachusetts Right to know

Substance(s) listed under Massachusetts Right to know:

No.

New Jersey Right to know

Substance(s) listed under New Jersey Right to know:

No

Pennsylvania Right to know

Substance(s) listed under Pennsylvania Right to know:

No.

#### **USA-FIFRA INFORMATION**

This chemical is a pesticide product registered by the Environmental Protection Agency and is subject to certain labeling requirements under federal pesticide law. These requirements differ from the classification criteria and hazard information required for safety data sheets, and for workplace labels of non-pesticide chemicals.

Following is the hazard information as required on the pesticide label:

CAUTION.

Harmful if swallowed.

Causes moderate eye irritation.

Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

#### 16. OTHER INFORMATION

Safety Data Sheet dated 3/11/2014, version 1

Disclaimer:

The information contained herein is based on our state of knowledge at the above-specified date. It refers solely to the product indicated and constitutes no guarantee of particular quality. The information relates only to the specific material and may not be valid for such material used in combination with any other material or in any process.

This Safety Data Sheet cancels and replaces any preceding release.

ADR: European Agreement concerning the International Carriage of

Dangerous Goods by Road.

CAS: Chemical Abstracts Service (division of the American Chemical Society).

CLP: Classification, Labeling, Packaging.

DNEL: Derived No Effect Level.

EINECS: European Inventory of Existing Commercial Chemical Substances.

GHS: Globally Harmonized System of Classification and Labeling of

Chemicals.

HMIS: Hazardous Materials Identification System
IARC: International Agency for Research on Cancer
IATA: International Air Transport Association.

IATA-DGR: Dangerous Goods Regulation by the "International Air Transport

Association\* (IATA).

ICAO: International Civil Aviation Organization.

ICAO-TI: Technical Instructions by the "International Civil Aviation Organization"

(ICAO).

IMDG: International Maritime Code for Dangerous Goods.
INCI: International Nomenclature of Cosmetic Ingredients.

KSt: Explosion coefficient.

LC50: Lethal concentration, for 50 percent of test population.

LD50: Lethal dose, for 50 percent of test population.

LTE: Long-term exposure.

NFPA: National Fire Protection Association

DENORA\_NACL/1 Page n. 6 of 7

#### Safety Data Sheet Sodium chloride

NIOSH: National Institute for Occupational Safety and Health

NTP:

National Toxicology Program
Occupational Safety and Health Administration OSHA:

PNEC: Predicted No Effect Concentration.

Regulation Concerning the International Transport of Dangerous Goods RID:

by Rail.

STE: Short-term exposure. STEL: Short Term Exposure limit. Specific Target Organ Toxicity. STOT: TLV: TWATLV:

Threshold Limiting Value.
Threshold Limit Value for the Time Weighted Average 8 hour day.

(ACGIH Standard).

DENORA\_NACL/1
Page n. 7 of 7

#### VI. Data Matrix



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# DATA MATRIX Date: EPA Reg No./ File Symbol Page 1 of 4 Applicant's/Registrant's Name and Address: Industrie De Nora S.p.A. c/o De Nora Tech 7590 Discovery Lane Concord, OH 44077 Ingredient: Sodium Chloride

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	End Note
Product Identity and Composition (Group A)					
830.1550	Product identity and composition		Industrie De Nora	Own	
830.1600	Description of materials used to produce the product		Industrie De Nora	Own	
830.1620	Description of production process		Industrie De Nora	Own	
830.1650	Description of formulation process		Industrie De Nora	Own	
830.1670	Discussion of formation of impurities		Industrie De Nora	Own	
830.1700	Preliminary analysis		Industrie De Nora	Own	
830.1750	Certified limits		Industrie De Nora	Own	
830.1800	Enforcement analytical method	Cite All		PL	
830.1900	Submittal of samples			As required	
Physical/Chemical Properties (Group B)					
830.6302	Color	Cite All		PL	1
830.6303	Physical state	Cite All		PL	1
830.6304	Odor	Cite All		PL	1
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	Cite All		PL	1

Signature:  Jack Ehle	Name and Title: Giorgio Padula, BU General Manager	Date February 13, 2015

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# DATA MATRIX Date: EPA Reg No./ File Symbol Page 2 of 4 Applicant's/Registrant's Name and Address: Industrie De Nora S.p.A. c/o De Nora Tech 7590 Discovery Lane Concord, OH 44077 Ingredient: Sodium Chloride

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	End Note
830.6314	Oxidation/reduction chemical incompatibility	Cite All		PL	1
830.6315	Flammability	Cite All		PL	1
830.6316	Explodability	Cite All		PL	1
830.6317	Storage stability	Cite All		PL	1
830.6319	Miscibility	Cite All		PL	1
830.6320	Corrosion characteristics	Cite All		PL	1
830.6321	Dielectric breakdown voltage	Cite All		PL	1
830.7000	pH	Cite All		PL	1
830.7050	UV/visible absorption	Cite All		PL	1
830.7100	Viscosity	Cite All		PL	1
830.7200	Melting point/melting range	Cite All		PL	1
830.7220	Boiling point/boiling range	Cite All		PL	1
830.7300	Density/relative density/bulk density	Cite All		PL	1
830.7370	Dissociation constants in water	Cite All		PL	1
830.7520	Particle size, fiber length, and diameter distribution	Cite All		PL	1
830.7550 830.7560 830.7570	Partition coefficient (n-octanol/water)	Cite All		PL	1

Signature:	Name and Title: Giorgio Padula, BU General Manager	Date February 13, 2015

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DATA MATRIX	
EPA Reg No./ File Symbol	Page 3 of 4
Product: Salt Cartridge for Giselle®	
	EPA Reg No./ File Symbol

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	End Note
830.7840 830.7860	Water solubility	Cite All		PL	1
830.7950	Vapor pressure	Cite All		PL	1
Product Performance					
810.2200	Disinfectants for use on hard surfaces – efficacy data		Industrie De Nora	OWN	
810.2300	Sanitizer for use on hard surfaces – efficacy data		Industrie De Nora	OWN	
Toxicity - Acute	THE RESERVE TO BE SHOWN THE PARTY OF THE PAR			THE PARTY OF	
870.1100	Acute oral toxicity - rat	Cite All		PL	2
870.1200	Acute dermal toxicity	Cite All		Waived	2
870.1300	Acute inhalation toxicity - rat	Cite All		Waived	2
870.2400	Acute eye irritation - rabbit	Cite All		PL	2, 3
870.2500	Acute dermal irritation	Cite All		PL	2, 3
870.2600	Dermal sensitization	Cite All		Waived	2
Toxicity - Subchronic					
870.3100	90-day oral toxicity - rodent	Cite All		Waived	2
Environmental Fate & Effects		Cite All		PL	4

Signature:	Name and Title:	Date
- Japa Ehlo	Giorgio Padula, BU General Manager	February 13, 2015

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	DATA MATRIX	
Date:	EPA Reg No./ File Symbol	Page 4 of 4
Applicant's/Registrant's Name and Address:		
Industrie De Nora S.p.A. c/o De Nora Tech 7590 Discovery Lane Concord, OH 44077	Product: Salt Cartridge for Giselle®	
Ingredient: Sodium Chloride		

- Reregistration Eligibility Decision (RED) Document, Inorganic Halides, List D, Case 4051 (Sept. 1993) and the Inorganic Halides Final Work Plan (FWP), Registration Review (Sept. 2009) lists the public literature that addresses these data requirements.
- RED at 7 "Because of its abundance in the environment and low toxicity to humans, no toxicity data were required for sodium chloride." Similarly, FWP at 8,
   "Therefore, the Agency does not believe that further toxicity data or exposure assessments for sodium chloride will be needed in association with this registration review."
- 3. Sax, N. I., and Lewis, R. J. Sr., (1989) Dangerous Properties of Industrial Materials. 7th Ed.
- 4. Reregistration Eligibility Decision Document, Inorganic Halides, List D, Case 4051 (Sept. 1993) at 9. "Sodium chloride occurs abundantly in the natural environment. It is a component of seawater, and in the diets of most terrestrial animal. Although it can be toxic in large amounts, especially to freshwater aquatic organisms, the use of sodium chloride as registered will not result in any significant exposure to non-target organisms in the environment. For the currently registered uses, sodium chloride is present in low amounts, or is used in indoor situations only. Since sodium chloride readily dissolves, no environmental fate assessment was necessary. Therefore, the Agency does not require any environmental fate of ecological effect, data for sodium chloride." See also FWP at 13 for similar conclusions.

Signature:	Name and Title: Giorgio Padula, BU General Manager	Date February 13, 2015

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

{Master Label} {Giselle Salt Cartridge} {February 13, 2015} {Optional/alternate language appears in [brackets]} {Page 1 of 11}

### Salt Cartridge For Giselle®



For Use Only in Giselle® Machine

### Produces Ready to Use Sanitizer or Disinfectant For hard, non-porous surfaces

Active Ingredient:	
Sodium Chloride*	99.86%
Other Ingredients:	0.14%
	Total: 100.00%

\*Produces 0.6%, 0.1%, and/or 0.05% available chlorine

# KEEP OUT OF REACH OF CHILDREN CAUTION

Read complete directions and precautions on the back panel and in manual

EPA Reg. No. 91386	EPA Est. No.
Net Contents: 80 grams	Mfg. by: Industries de Nora, S.p. A Via Bistolfi 35 20134 Milan, Italy

{Master Label} {Giselle Salt Cartridge} {February 13, 2015} {Optional/alternate language appears in [brackets]} {Page 2 of 11}

#### DIRECTIONS FOR USE:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

- · Dry, Ready-to-Use
- Shake vigorously before use.
- Remove the cap and insert the cartridge in Giselle® cartridge compartment without removing the protective foil.
- · Gently tap the cartridge bottom, to facilitate salt crystals flow.
- Do not use if the cartridge or the protective foil are damaged.

#### STORAGE AND DISPOSAL:

Do not contaminate water, food, or feed by storage.

Pesticide Storage: Store this product in a cool dry area, away from direct sunlight and heat to

avoid deterioration. In case of spill, flood areas with large quantities of water.

Pesticide Disposal: Product or rinsates that cannot be used must be diluted with water before

disposal in a sanitary sewer.

Container Handling: Nonrefillable container. Do not reuse or refill this container. Offer for reconditioning if appropriate. Wrap empty container in paper and dispose with trash.

# PRIA 3 – 21 Day Content Screen Review Worksheet (EPA/OPP Use Only) September 2012

PA	Reg. Number: 91386-R EPA Receipt Date: 2-	18-	15			
	Items for Review			Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete include type	ding pac	kage	X		
•	Confidential Statement of Formula all boxes completed, form s dated (EPA Form 8570-4)	signed, a	nd	X		
2	a) All inerts, including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
3	Certification with Respect to Citation of Data (EPA Form 8570 completed and signed (N/A if 100% repack)	)-34)		X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use or	nly.				
4	Formulator's Exemption Statement (EPA Form 8570-27) compsigned (N/A if source is unregistered or applicant owns the technic		d			X
	Data Matrix (EPA Form 8570-35) both internal and external cop completed and signed (N/A if 100% repack)	ies (PR	<u>98-5</u> )	X		
5	a) Selective Method (Fee category experts use)	yes	no			
	b) Cite-All (Fee category experts use)	~				
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of <u>Label</u> ( <u>Electronic labels on CD</u> are encouraged and available)	d guida	nce is	X		
7	Is the data package consistent with PR Notice 86-5		-16			
8	Notice of Filing included with petitions					X

9	If applicable for conventional applications, reduced risk rationale	K
	Required Data and/or data waivers. See Footnote C.	
	a) List study (or studies) not included with application	
10		
Com	ments:  * Documentation: PASS FAT L  required forms are complete	
	A Inerts: (PAJ) I FAIL  . no Therb to review	
	* PRN 11-3: PAN) PAZL	
	MRZD: 495733 . 49573311 & 49573320 have They the project. Contacted Submether a - Recented documents on 3-9-15	. 3-4-15.
	* Overall Status: PASS / FAZL	
אל	3-975	

#### Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are strongly encouraged to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency even if a product is currently registered by consulting the inert Web site and if the inert is not approved nor has an application pending with the Agency, to obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at <a href="inertsbranch@epa.gov">inertsbranch@epa.gov</a> and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the <a href="Chief of Microbial Pesticides Branch">Chief of Microbial Pesticides Branch</a>.

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

#### **Unapproved Inerts Identified on CSFs**

#### All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

- Correct the application by, for instance, correcting the inert's identity or CAS
  number, providing documentation that the inert has been approved, or
  removing the unapproved inert from the CSF or replacing it with one that is
  approved for the application's uses; or
- 2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
- 3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
- 4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

#### Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

- 1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
- 2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

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3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

#### PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

- 1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
- 2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
- 3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

- B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.
- C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

#### Kang, Ji Yeon

From: Sheryl Dolan <sdolan@actagroup.com>
Sent: Monday, March 09, 2015 11:34 AM

To: Downs, Teresa

Cc: Kang, Ji Yeon; Ashe, Anthony; Clausen, Kirk

Subject: FW: Submission to EPA: Salt Cartridge for Giselle® (EPA Reg. No. 91386-R)

**Attachments:** 00154336.PDF; 00154334.PDF

#### Teresa:

Thank you very much for your assistance this morning, as always. I have attached to this e-mail two files, containing the replacement pages requested in the e-mail string below:

For MRID 49573311, Volume 12, pages 18-20, document number 154336; and

For MRID 49573320, Volume 21, page 18, document number 154334.

These versions of these pages print legibly. Please advise if they do not for EPA, in which case would be pleased to hand-deliver hard copies.

Thank you and best regards,

#### SHERYL LINDROS DOLAN

ACTA ASIA | EUROPE | THE AMERICAS

2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037 T: 202-266-5031 | F: 202-557-3836 | actagroup.com

From: Kang, Ji Yeon [mailto:Kang.Joyce@epa.gov] Sent: Wednesday, March 04, 2015 2:44 PM

To: Sheryl Dolan

Subject: RE: Submission to EPA: Salt Cartridge for Giselle® (EPA Reg. No. 91386-R)

MRID 49573311 is Volume # 12 Study # S-2013-02014-AMI Rev2 MRID 49573320 is Volume #21 Study # S-2013-02010-AMi Rev2

From: Sheryl Dolan [mailto:sdolan@actagroup.com]

Sent: Wednesday, March 04, 2015 2:36 PM

To: Kang, Ji Yeon

Subject: RE: Submission to EPA: Salt Cartridge for Giselle® (EPA Reg. No. 91386-R)

Ms. Kang:

As there are two studies with very similar names and we do not yet have a copy of the Transmittal Document with the MRID numbers, please clarify whether the second study listed below (MRID49573320) is Report No. 2012/1686 Ami Rev1, Volume 19 in the submission, or Report No. S-2013-02010 Ami Rev2, Volume 21 in the submission.

Many thanks,

#### SHERYL LINDROS DOLAN

ACTA ASIA | EUROPE | THE AMERICAS

2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037

T: 202-266-5031 | F: 202-557-3836 | actagroup.com



From: Kang, Ji Yeon [mailto:Kang.Joyce@epa.gov]
Sent: Wednesday, March 04, 2015 10:15 AM

To: Sheryl Dolan

Cc: Ashe, Anthony; Clausen, Kirk

Subject: Submission to EPA: Salt Cartridge for Giselle® (EPA Reg. No. 91386-R)

Dear Ms. Dolan

My name is Joyce Kang and I am a contractor with the EPA. I am contacting you in regards to your submission in support of the product Salt Cartridge for Giselle® (EPA Reg. No. 91386-R). We have found few deficiencies with the submission that will need to be addressed:

- For study MRID49573311 "Evaluation of In Vitro Quantitative Virucidal Efficacy against Human Immunodeficiency Virus (HIV-1) on Giselle and Soleva Solutions," the pages 18-20 in the study are illegible due to the poor quality of the photocopying.
- For study MRID49573320 "Evaluation of Sanitizing Bactericidal Efficacy against S. aureus and K. pneumoniae for Non-Food and Food Hard Non-Porous Surfaces on Giselle and Soleva Solutions," the page 18 in the study is illegible due to the poor quality of the photocopying.

Please send the revised documents before Mar 11<sup>th</sup> so that we may further process your submission. After Mar 11<sup>th</sup>, please direct all correspondence/corrections to the appropriate EPA Risk Manager. If you have any questions, please do not hesitate to contact me.

Kind Regards,

Joyce Kang

Contractor, US EPA 2777 S. Crystral Drive, S-4822 Arlington, VA 22202 (703) 347-0416 Email: kang.joyce@epa.gov

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## A540 - New end use product.

 Must submit or reference Group A and B product chemistry, toxicity, and/or efficacy data for each proposed product.

 Data waivers may be requested. Chemistry data on the TGAI in addition to the EP is required if an unregistered source is used.

End Use (EP) or Manufacturing Use (MP) product or Technical Grade of the Active Ingredient (TGAI)

Guideline No.	Group A: Product Chemistry Data Study Title	EP Data Submitted	MP Data Submitted	TGAI Data Submitted
830.1550	Product Identity & Composition		V	
830.1600	Description of materials used to produce the product		L	
830.1650	Description of formulation process		L	
830.1670	Discussion on the formation of impurities		V	
830.1700	Preliminary analysis		V	
830.1750	Certified limits (158.345)		·	
830.1800	Enforcement analytical method		V	

Guideline No.	Group B: Product Chemistry Data Study Title	EP Data Submitted	MP Data Submitted	TGAI Data Submitted
830.6302	Color		V	
830.6303	Physical State			
830.6304	Odor		L	
830.6313	Stability to normal and elevated temperatures metal and metal ions			
830.6314	Oxidation/Reduction (Chemical incompatibility)		c	
830.6315	Flammability		v .	
830.6316	Explodability		·v	
830.6317	Storage stability*		V	
830.6319	Miscibility		L	
830.6320	Corrosion Characteristics*		-	
830.6321	Dielectric Breakdown Voltage			
830.7000	pH	The state of the s	V	
830.7050	UV/ Visible Absorption			
830.7100	Viscosity		V	
830.7200	Melting Point			
830.7220	Boiling Point			
830.7300	Density		V	
830.7370	Dissociation Constant			
830.7550	Partition Coefficient			
830.7840	Water Solubility	W. Harris		1
830.7950	Vapor Pressure			

Grayed out = data not required

\*May not be included with initial application

# **A540 – Acute Toxicity Requirements**

New products must either:

1) supply the product specific acute toxicity 6 pack data (listed below),

2) provide a bridging rationale document or waiver request or,

3) use the cite all method of data compensation, if applicable. The bridging document directs OPP to use a currently registered set of 6 acute toxicity data and label; instead of submitting product specific data.

Guideline No.	Acute toxicity (6 pack) Study Title	Cite All	Selective	Waiver Request	Bridging Rational
830.1100	Acute Oral (LD50)	V			
830.1200	Acute Dermal (LD50)	-			
830.1300	Acute Inhalation (LC50)	6			
830.2400	Acute Eye Irritation	V			
830.2500	Acute Dermal Irritation	V			FILLER
830.2600	Dermal Sensitization	V			

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# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

February 24, 2015

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

OPP Decision Number: D-500221

EPA File Symbol or Registration Number: 91386-R Product Name: SALT CARTRIDGE FOR GISELLE

EPA Receipt Date: 18-Feb-2015 EPA Company Number: 91386

Company Name: INDUSTRIE DE NORA, S.P.A.

SHERYL LINDROS DOLAN
THE ACTA GROUP, LLC
INDUSTRIE DE NORA, S.P.A.
2200 PENNSYLVANIA AVE., NW, SUITE 100W
WASHINGTON, DC 20037-1701

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: A540

NEW PRODUCT; NON-FAST TRACK; FIFRA SEC. 2(MM) USES;

No additional payment is due at this time.

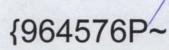
If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 347-0228.

Sincerely,

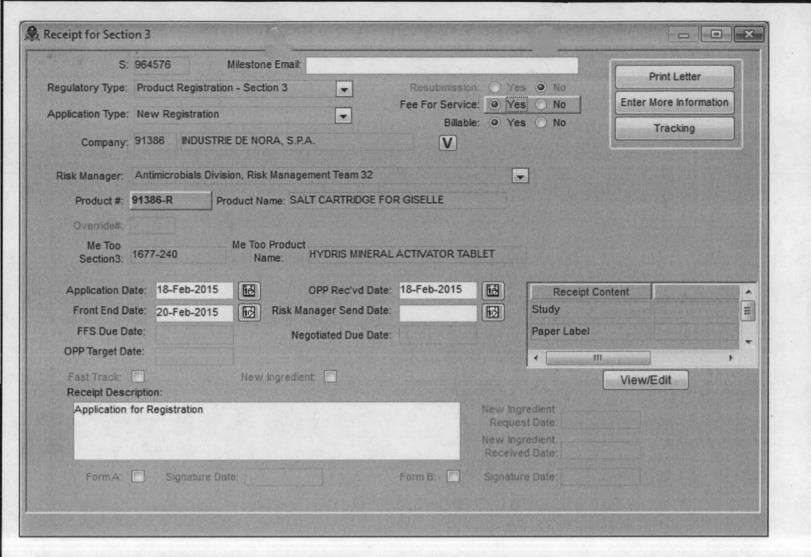
Front End Processing Staff

Information Technology & Resources Management Division

# Fee for Service



This package includes the following	for Division		
<ul><li>New Registration</li><li>Amendment</li></ul>	AD     BPPD     RD		
<ul><li>Studies? □ Fee Waiver?</li><li>□ volpay % Reduction:</li></ul>	Risk Mgr. 32		
Receipt No. S- EPA File Symbol/Reg. No. Pin-Punch Date:	964576 91386-R 2/18/2015		
This item is NOT subject to	to FFS action.		
Action Code:  Requested: ASYO  Amount Due: \$ 4863.00	Parent/Child Decisions:		
■ Inert Cleared for Intended Use	Uncleared Inert in Product		
Reviewer: 1em	Date: 2-23-/5		
Remarks:			



#### IV. Receipt of Fee Payment

----Messaggio originale----

Da: pay.gov.clev@clev.frb.org [mailto:pay.gov.clev@clev.frb.org]

Inviato: mercoledì 17 dicembre 2014 08:40

A: Padula Giorgio

Oggetto: Pay.gov Payment Confirmation: PRIA Service Fees

Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Michael Yanchulis at (703) 347-0237 or by email at yanchulis.michael@epa.gov.

Application Name: PRIA Service Fees

Pay.gov Tracking ID: 25ITUFVA Agency Tracking ID: 74723650255

Transaction Type: Sale

Transaction Date: 12/17/2014 02:39:38 AM EST

Account Holder Name: Industrie De Nora s.p.a.

Transaction Amount: \$4,863.00

Billing Address: Via Leonardo Bistolfi, 35

Billing Address 2:

City: Milano

State/Province: Milano Zip/Postal Code: 20134

Country: ITA Card Type: Visa

Card Number: \*\*\*\*\*\*\*\*\*3521

Registration Number:

Company Name: Industrie De Nora S.p.A.

Company Number: 91386 Action Code: A540

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

## III. Application for Pesticide Registration

rse before completing fo	irm.			Form A	Approved. OMB No. 2070-0060.
nvironmental F	rotection			Registratio Amendmen Other	
Appli	cation fo	r Pesticide - S	Section	11	
					3. Proposed Classification
		PM# 32			None ☐ Restricted
		EPA Reg. No.	1677	cal in composition	and labeling to:
W 300100	S	ection - II			
nse to Agency letter date		Final pri Agency Me Too	etter date Applicati	ion.	
registration of sodiu	m chloride fo s category A	or use in the Giselle 532 with a fee of \$4			
la Packanad In-	26	ction - III			
Unit Packaging Yes No		Water Soluble Pack Yes No	kaging		stainer fetal flastic
If "Yes" Unit Packaging wgt.	No. per container				Blass Paper Other (Specify)
	4. Size(s) F	Retail Container	1	On Label	el Directions accompanying product
Affixed to Product		Lithograph Paper glued Stenciled	0	ther	
	Se	ction - IV			
	tification of inc		d, if neces		
Re	egulatory Spo	ecialist		202-266-5	
we made on this form ar	nd all attachm			and complete.	. Date Application Received (Stamped)
2. Signature  3. Title BU General Manag					
		15			
	United Invironmental F Washingto  Appli  Appli  Appli  Appli  ant (Include Zip Code)  ew address  elow.  age(s) if necessary. (Fee registration of sodiument of s	Application for Application for Application for Application for Application for ant (Include Zip Code)  ew address  selow.  Inse to Agency letter dated allow.  Inse to Agency	United States (Invironmental Protection Agency Washington, DC 20460  Application for Pesticide - S  2. EPA Product Demson Fulle  PM#  32  ant (Include Zip Code)  6. Expedited 8 product is simility EPA Reg. No. Product Name ew address  Section - II  elow. Section - II  elow. Section - III  elow. Section - III  elow. Section - III  Be Packaged In: Unit Packaging Yes No No If "Yes" Unit Packaging wgt. No. per Unit Packaging wgt. No. per Unit Packaging wgt.  No. per Unit Packaging wgt.  No. per Unit Packaging wgt.  Affixed to Product  Lithograph Package wgt Section - IV  stille Regulatory Specialist Certification of individual to be contacted Title Regulatory Specialist Certification of we made on this fearing statements thereto are true, by false or misleading statement may be punishable by fine  Section - IV  stille Regulatory Specialist Certification of individual to be contacted Title Regulatory Specialist Certification of individual to be contacted Title Regulatory Specialist Certification of individual to be contacted Title Regulatory Specialist Certification of individual to be contacted Title Regulatory Specialist Certification of individual to be contacted Title Regulatory Specialist Certification of individual to be contacted Title Regulatory Specialist Certification of individual to be contacted Title Regulatory Specialist Certification of individual to be contacted Title Regulatory Specialist Certification of individual to be contacted Title Regulatory Specialist Certification of individual to be contacted Title Regulatory Specialist Certification of individual to be contacted Title Regulatory Specialist Certification Office Specialist Of	United States Invironmental Protection Agency Washington, DC 20460  Application for Pesticide - Section  2. EPA Product Manager Demson Fuller  PM# 32  ant (Include Zip Code)  6. Expedited Review. In product is similar or ident EPA Reg. No	United States Invironmental Protection Agency Washington, DC 20460  Application for Pesticide - Section I  2. EPA Product Manager Demson Fuller  PM# 32  ant (Include Zip Code)  8. Expedited Review. In accordance with product is similar or identical in composition EPA Reg. No1677-240 Product NameHydris Mineral Activa Product Name

#### I. Transmittal Letter/Document



February 18, 2015

Via Hand Delivery

Mr. Demson Fuller
U.S. Environmental Protection Agency
Pesticide Document Processing Center
7504P, Room S-4900
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Re: Industrie De Nora S.p.A. Registration Application for Salt Cartridge for Giselle®, EPA Reg. No. 91386-R

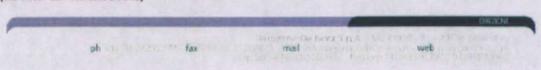
Dear Demson:

Industrie De Nora S.p.A. (De Nora) is pleased to submit the accompanying application to register its sodium chloride product, Salt Cartridge for Giselle<sup>®</sup>. As you know, De Nora has been engaged with the U.S. Environmental Protection Agency (EPA) Office of Pesticide Programs (OPP) for more than a year to discuss this product and its registration application. As a result of this engagement, De Nora's application includes robust data and other information responsive to OPP's inquiries and according to OPP's guidance. Related correspondence with OPP is included in Volume 1 of the submission. A transmittal document that lists the submission's 25 volumes is attached to this letter.

De Nora expects OPP will place the registration application into Pesticide Registration Improvement Extension Act category A540. A receipt for the fee payment also is included in Volume 1 of the submission.

As discussed with OPP, De Nora seeks to register sodium chloride as a precursor chemical that De Nora intends to use in conjunction with De Nora's Giselle<sup>®</sup> machine. The Giselle<sup>®</sup> machine converts the registered precursor chemical to produce ready-to-use sodium hypochlorite solutions for use as a sanitizer (0.05 percent and 0.1 percent concentrations) or disinfectant (0.6 percent concentration). Although sodium hypochlorite is an existing active ingredient with already well-documented efficacy as a sanitizer and disinfectant, the Giselle<sup>®</sup> technology for preparing unbuffered solutions of sodium hypochlorite is novel. The unbuffered solutions pose reduced potential hazard to users because their pH are closer to neutral than buffered solutions, but the hypochlorite has a shorter shelf life. The Giselle<sup>®</sup> technology

{01243.002 / 111 / 00151862.DOC 12}





Mr. Demson Fuller February 18, 2015 Page 2

therefore allows users to produce single-use amounts of disinfectant or sanitizer for immediate use and prints an expiration sticker for each bottle of solution produced.

In its Reregistration Eligibility Decision (RED) for Sodium and Calcium Hypochlorite Salts, EPA states:

> The Agency has decided to continue its current policy of waiving the product-by-product efficacy data requirement normally levied on sanitizers and disinfectants for sodium and calcium hypochlorite formulations. The Agency has concluded that the published literature data can reasonably be extrapolated to the full range of these products.

De Nora has conducted and submits for EPA's review several efficacy studies according to EPA's guidelines to support claims against additional specific target organisms. The efficacy studies comprise Volumes 10 through 25 of this submission. A summary overview of these studies is presented in Volume 9.

In response to the OPP inquiry, De Nora also provides data in Volume 7 of this submission to address the reliability of its Giselle® technology to produce the sodium hypochlorite solutions within specification over the equipment's lifetime. OPP also requested concentration data for sodium hypochlorite solutions produced by at least five different machines to demonstrate reliability. These data are included in Volume 8.

De Nora's product proposed for registration consists of commodity, pharmaceutical-grade sodium chloride. De Nora submits in Volume 3 five certificates of analysis and related information from the supplier. De Nora is using the cite-all method of support for its registration application.

In addition to the five certificates of analysis for the sodium chloride, De Nora has provided analyses of the sodium hypochlorite solutions at each concentration, produced using water with a range of hardness levels. These analyses are presented in Volumes 4 through 6.

De Nora also includes in Volume 1 five copies of the proposed label for the registered sodium chloride precursor product and copies of proposed labeling for the disinfectant and sanitizer solutions, which themselves will not be sold or distributed in commerce.

{01243.002 / 111 / 00151862 DOC 12}



Mr. Demson Fuller February 18, 2015 Page 3

If there are any questions or comments concerning this registration application, please call The Acta Group (Acta): Sheryl Lindros Dolan, at (202) 266-5031, or Henry M. (Hank) Jacoby at (301) 865-9090. A copy of the previously submitted Letter of Authorization for OPP to speak with Acta is included in Volume 1.

Sincerely,

Joseph Edula

Giorgio Padula BU General Manager

Attachments

cc: Mr. Richard Lance Wormell, EPA (w/o attachments)
Mara Bagnasco, De Nora
Assunta Rossi, Esquire, De Nora Tech
Lisa M. Campbell, Acta
Sheryl L. Dolan, Acta
Henry M. Jacoby, Acta

{01243.002 / 111 / 00151862.DOC 12}

#### **Transmittal Document**

#### Name and Address of Submitter:

Industrie De Nora, S.p.A.

De Nora Tech 7590 Discovery Lane Concord, OH 44077 Company No.:

91386

Contact Person: Title: Giorgio Padula BU General Manager +39 (02) 212-92270

E-Mail:

Telephone:

giorgio.padula@denora.it

#### Individual to be contacted, if necessary, to process this application:

The Acta Group, L.L.C.

2200 Pennsylvania Avenue, N.W. Suite 100W Contact Person: Telephone: Sheryl Lindros Dolan

Telephone:

(202) 266-5031 (202) 557-3836

Washington, D.C. 20037-1701

E-Mail:

sdolan@actagroup.com

Regulatory Actions: Submission of an application for registration for a new antimicrobial product, Salt Cartridge for Giselle®.

Transmittal Date:

February 18, 2015

#### List of Submitted Studies:

Vol.	Contents	Guideline No.	Study Report Title	MRID No.
1	Administrative: New Product Registration	N/A	Application for Registration of Salt Cartridge for Giselle®, Report No. 1243-02-001	
2	Product Chemistry	830.1550 830.1600 830.1620 830.1670 830.1750 830.1800	Product Chemistry in Support of Salt Cartridge for Giselle®, Report No. 1243-02-002	
3	Preliminary Analysis	830.1700	Salt Cartridge for Giselle® - Sodium Chloride - Preliminary Analysis, Report No. 1243-02- 003	
4	Preliminary Analysis and Stability	830.1700 830.6317	Preliminary Analysis and Stability for Soleva™ 0.6% Solution Produced from Salt Cartridge for Giselle® in a Range of Water Hardness, Report No. 1243-02-004	

Vol.	Contents	Guideline No.	Study Report Title	MRID No.
5	Preliminary Analysis and Stability	830.1700 830.6317	Preliminary Analysis and Stability for Soleva <sup>TM</sup> 0.05% Solution Produced from Salt Cartridge for Giselle <sup>®</sup> in a Range of Water Hardness, Report No. 1243-02-005	
6	Preliminary Analysis and Stability	830.1700 830.6317	Preliminary Analysis and Stability for Soleva™ 0.1% Solution Produced from Salt Cartridge for Giselle® in a Range of Water Hardness, Report No. 1243-02-006	
7	Life Cycle Testing	N/A	Life Cycle Testing for Soleva <sup>TM</sup> Solutions Produced by the Giselle <sup>®</sup> Equipment, Report No. 1243-02-007	
8	Validation of Production Efficiency and Reproducibility	N/A	Validation of Production Efficiency and Reproducibility by the Giselle® Equipment, Report No. 1243-02-008	
9	Efficacy Data Summary and Certification of Water Hardness	N/A	Efficacy Data Summary and Certification of Water Hardness, Report No. 1243-02- 009	
10	Efficacy Data: Disinfectants for Use on Hard Surfaces	810.2100	Evaluation of <i>In Vitro</i> Quantitative Sporicidal Efficacy Against <i>Clostridium Difficile</i> on Giselle® and Soleva Solutions, Report No. S-2013- 02013 AMi Rev2	
11	Efficacy Data: Disinfectants for Use on Hard Surfaces	810.2200	Evaluation of Disinfectant Efficacy for Broad-Spectrum and Hospital or Healthcare Spectrum on Hard Non-porous Surfaces on Giselle® and Soleva Solutions, Report No. S- 2013-02012 AMi Rev1	
12	Efficacy Data: Disinfectants for Use on Hard Surfaces	810.2200	Evaluation of <i>In Vitro</i> Quantitative Virucidal Efficacy Against <i>Human Immunodeficiency Virus (HIV-1)</i> on Giselle® and Soleva Solutions, Report No. S-2013-02014 AMi Rev2	

Vol.	Contents	Guideline No.	Study Report Title	MRID No.
13	Efficacy Data: Disinfectants for Use on Hard Surfaces	810.2200	Evaluation of Fungicidal Efficacy Against Trychophyton mentagrophytes on Hard Non- porous Surfaces on Giselle® and Soleva Solutions, Report No. S-2013-02016 AMi Rev1	
14	Efficacy Data: Disinfectants for Use on Hard Surfaces	810.2200	Evaluation of Disinfectant Efficacy for Broad-Spectrum and Hospital or Healthcare Spectrum on Hard Non-porous Surfaces on Giselle® and Soleva Solutions, Report No. 2012/1681 AMi Rev1	
15	Efficacy Data: Disinfectants for Use on Hard Surfaces	810.2200	Evaluation of Fungicidal Efficacy Against Trychophyton mentagrophytes on Hard Non- porous Surfaces on Giselle® and Soleva Solutions, Report No. 2012/1682 AMi Rev1	
16	Efficacy Data: Disinfectants for Use on Hard Surfaces	810.2200	Evaluation of In Vitro Quantitative Virucidal Efficacy Against Poliovirus on Giselle and Soleva Solutions, Report No. 2012/1683 AMi Rev1	
17	Efficacy Data: Disinfectants for Use on Hard Surfaces	810.2200	Evaluation of In Vitro Quantitative Virucidal Efficacy Against Feline Calicivirus on Giselle® and Soleva Solutions, Report No. 2012/1684 AMi Rev1	
18	Efficacy Data: Disinfectants for Use on Hard Surfaces	810.2200	Evaluation of In Vitro Quantitative Virucidal Efficacy Against Bovine Viral Diarrhea Virus on Giselle® and Soleva Solutions, Report No. 2012/1685 AMi Rev1	
19	Efficacy Data: Sanitizer for Use on Hard Surfaces	810.2300	Evaluation of Sanitizing Bactericidal Efficacy Against S. aureus and K. pneumoniae for Non-food and Food Hard Non- porous Surfaces on Giselle <sup>®</sup> and Soleva Solutions, Report No. 2012/1686 AMi Rev1	

Vol.	Contents	Guideline No.	Study Report Title	MRID No.
20	Efficacy Data: Sanitizer for Use on Hard Surfaces	810.2300	Evaluation of the Available Chlorine as Germicidal Equivalent Concentration Against S. aureus on Giselle® and Soleva Solutions, Report No. 2012/1687 AMi Rev1	
21	Efficacy Data: Sanitizer for Use on Hard Surfaces	810.2300	Evaluation of Sanitizing Bactericidal Efficacy Against S. aureus and K. pneumoniae for Non-food and Food Hard Non- porous Surfaces on Giselle® and Soleva Solutions, Report No. S-2013-02010 AMi Rev2	
22	Efficacy Data: Sanitizer for Use on Hard Surfaces	810.2300	Evaluation of Sanitizing Bactericidal Efficacy for Non- food and Food Hard Non- porous Surfaces on Giselle® and Soleva Solutions, Report No. S-2013-02191 AMi Rev1	
23	Efficacy Data: Sanitizer for Use on Hard Surfaces	810.2300	Evaluation of the Available Chlorine as Germicidal Equivalent Concentration Against S. aureus on Giselle® and Soleva Solutions, Report No. S-2013-02011 AMi Rev1	
24	Efficacy Data: Sanitizer for Use on Hard Surfaces	810.2300	Evaluation of Sanitizing Bactericidal Efficacy for Non- food and Food Hard Non- porous Surfaces on Giselle® and Soleva Solutions, Report No. S-2014-01594 AMi	
25	Efficacy Data: Sanitizer for Use on Hard Surfaces	810.2300	Evaluation of the Available Chlorine as Germicidal Equivalent Concentration Against S. aureus on Giselle® and Soleva Solutions, Report No. S-2014-01595 AMi Rev1	

#### II. Summary of the Application

Industrie De Nora, S.p.A. (De Nora) is submitting this application for registration of a sodium chloride (salt) cartridge intended for use in the Giselle® machine to produce 0.6%, 0.1%, and 0.05% solutions of ready-to-use sodium hypochlorite for use as a hard surface disinfectant (0.6%) and sanitizer (0.1% and 0.05%). Although sodium hypochlorite is an existing active ingredient with already well-documented efficacy as a sanitizer and disinfectant, the Giselle® technology for preparing unbuffered solutions of sodium hypochlorite is novel. The unbuffered solutions pose reduced potential hazard to users because their pH are closer to neutral than buffered solutions, but the hypochlorite has a shorter shelf life. The Giselle® technology therefore allows users to produce single-use amounts of disinfectant or sanitizer for immediate use and prints an expiration sticker for each bottle of solution produced.

De Nora is using the cite-all method of support for its registration application. As it states in the Reregistration Eligibility Decision (RED)<sup>1</sup> and registration review documents for sodium chloride, the U.S. Environmental Protection Agency (EPA) has waived all mammalian toxicity data, except for acute oral toxicity and primary eye and skin irritation, and all environmental and ecological data. Pertinent excerpts from these documents appear below. De Nora is relying on the data in EPA's files, which EPA discusses thoroughly in the RED and sodium chloride registration review documents.

In its 2009 Final Work Plan, EPA states the following:

Sodium chloride (commonly known as salt, sea salt and table salt) is abundant in nature and is commonly used to season or preserve food. Sodium chloride is generally recognized as safe (GRAS) (21 CFR § 184.1426) by the U.S. Food and Drug Administration (FDA). Sodium chloride is an essential constituent of the body, present in many foods, and in water dissociates completely into sodium and chloride ions. Therefore, the Agency does not believe that further toxicity data or exposure assessment for sodium chloride will be needed in association with this registration review.<sup>2</sup>

{01243.002 / 111 / 00137611.DOC 7} Page 12 of 171 Report No. 1243-02-001 **73** 

EPA, Reregistration Eligibility Decision (RED) for Inorganic Halides, (Sept. 1993), available at <a href="http://www.epa.gov/opp00001/chem\_search/reg\_actions/reregistration/red\_G-48\_1-Sep-93.pdf">http://www.epa.gov/opp00001/chem\_search/reg\_actions/reregistration/red\_G-48\_1-Sep-93.pdf</a>.

EPA, *Inorganic Halides Final Work Plan*, *Registration Review* (Sept. 2009), available at <a href="http://www.regulations.gov/contentStreamer?objectId=0900006480a290c5&disposition=attachment&contentType=pdf">http://www.regulations.gov/contentStreamer?objectId=0900006480a290c5&disposition=attachment&contentType=pdf</a>.

Similarly, in its Inorganic Halides RED Fact Sheet, EPA states the following:

Sodium chloride is of low acute oral toxicity and causes moderate eye irritation; it has been placed in Toxicity Category III for these effects. It causes mild skin irritation and for this effect has been placed in Toxicity Category IV.

Sodium chloride, known as salt, sea salt and table salt, is abundant in nature. It is used primarily to season or preserve food and is consumed by people daily, especially in commercially prepared and preserved foods. Consumption of more than the minimum daily requirement of salt may contribute to high blood pressure in some populations. ...

...EPA did not perform an environmental assessment of sodium chloride. The registered uses result in insignificant exposure to the environment. Sodium chloride occurs abundantly in the natural environment. It is a component of seawater, and is in the diets of most terrestrial animals. Although it can be toxic in large amounts, especially to freshwater aquatic organisms, the use of sodium chloride as registered will not result in any significant exposure to non-target organisms in the environment.<sup>3</sup>

Additionally, in its Reregistration Eligibility Decision (RED) for Sodium and Calcium Hypochlorite Salts, EPA states:

The Agency has decided to continue its current policy of waiving the product-by-product efficacy data requirement normally levied on sanitizers and disinfectants for sodium and calcium hypochlorite formulations. The Agency has concluded that the published literature data can reasonably be extrapolated to the full range of these products.<sup>4</sup>

De Nora has conducted and submits for EPA's review several efficacy studies according to EPA's guidelines to support claims against additional specific target organisms. A complete list of the efficacy studies and other data submitted in support of this registration appears in the transmittal document and is discussed in the transmittal letter for this submission. Copies of these documents are included in this Volume for ease of reference.

{01243.002 / 111 / 00137611.DOC 7} Page 13 of 171 Report No. 1243-02-001

EPA, RED FACTS Inorganic Halides, (Sept. 1993), available at <a href="http://www.epa.gov/opp00001/chem\_search/reg\_actions/reregistration/fs\_G-48\_1-Sep-93.pdf">http://www.epa.gov/opp00001/chem\_search/reg\_actions/reregistration/fs\_G-48\_1-Sep-93.pdf</a>.

EPA, Reregistration Eligibility Decision (RED) for Sodium and Calcium Hypochlorite Salts, (Feb. 1992), available at <a href="http://www.epa.gov/opp00001/chem\_search/reg\_actions/reregistration/red\_G-77\_1-Feb-92.pdf">http://www.epa.gov/opp00001/chem\_search/reg\_actions/reregistration/red\_G-77\_1-Feb-92.pdf</a>.

#### V. Certification with Respect to Citation of Data



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		totection Agency, 1200 Pennsylvania Avenue, N.W., Washington,
DC 20460. Do not send the completed form to this address.		
CERTIFICATION	WITH RESPECT	TO CITATION OF DATA
Applicant's/Registrant's Name, Address, and Telephone Number Industrie De Nora, S.p.A. c/o De Nora Tech 7590 Discovery Lane Concord, OH 44077 Attention: Legal Department (440) 710-5300		EPA Registration Number/File Symbol
Active Ingredient(s) and/or representative test compound(s) Sodium Chloride		Date February 13, 2015
need to submit this form. You must submit the Formulator's  I am responding to a Data-Call-In Notice, and have	Exemption Statement (	ed product labeled for all the same uses on your label, you do not (EPA Form 8570-27). rm a list of companies sent offers of compensation (the Data Matrix
form should be used for this purpose).	OD OF DATA SUB	POPT (73-14-11-)
with this form a list of companies sent offers of compensation  (the Data Matrix forms chould be used for this represent)		I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
SECTIO	ON II: GENERAL O	FFER TO PAY
	persons, with regard to the	approval of this application, to the extent required by FIFRA.
	CTION III: CERTII	
method is indicated in Section I, this application is supported by identical or substantially similar product, or one or more of the the data requirements in effect on the date of approval of this apcomposition and uses.	ata-Call-In response. In a y all data in the Agency's ingredients in this produ oplication if the application is registration or reregistr.	all-lin response is supported by all data submitted or cited in the addition, if the cite-all option or cite-all option under the selective files that (1) concern the properties or effects of this product or an ct; and (2) is a type of data that would be required to be submitted under on sought the initial registration of a product of identical or similar ation, that I am the original data submitter or that I have obtained the
I have obtained the permission of the original data submitter to expired for the study; (d) the study is in the public literature; or compensation to the extent required by sections 3(c)(1)(F) and/or compensation, if any, to be paid for the use of the study.  I certify that in all instances where an offer of compensation is a with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available the Agency upon request, I understand that the Agency may init I certify that the statements I have made on this form and all att	use the study in support (e) I have notified in writer 3(c)(2)(B) of FIFRA; arequired, copies of all office and will be submitted tiste action to deny, cancularly the submitted to the submitted	of an exclusive use study, either: (a) I am the original data submitter; (b) of this application; (c) all periods of eligibility for compensation have ting the company that submitted the study and have offered (I) to pay and (ii) to commence negotiations to determine the amount and terms of terms to pay compensation and evidence of their delivery in accordance to the Agency upon request. Should I fail to produce such evidence to el or suspend the registration of my product in conformity with FIFPA.
misleading statement may be punishable by fine or imprisonme Signature	Date February 13, 2015	ole law.  Typed or Printed Name and Title  Giorgio Padula, BU General Manager

EPA Form 8570-34 (12-2003) Electronic and Paper versions available. Submit only Paper version



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# DATA MATRIX Date: EPA Reg No./ File Symbol Page 1 of 4 Applicant's/Registrant's Name and Address: Industrie De Nora S.p.A. c/o De Nora Tech 7590 Discovery Lane Concord, OH 44077 Ingredient: Sodium Chloride

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	End Note
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Signature:		Name and		Date	
Japa Ehla		Giorgio Pa	adula, BU General Manager	Febru	ary 13, 2015

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# DATA MATRIX Date: EPA Reg No./ File Symbol Page 2 of 4 Applicant's/Registrant's Name and Address: Industrie De Nora S.p.A. c/o De Nora Tech 7590 Discovery Lane Concord, OH 44077 Ingredient: Sodium Chloride

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	End Note
				PL	1
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Signature:	Name and Title:	Date
Japa Ehla	Giorgio Padula, BU General Manager	February 13, 2015

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# DATA MATRIX Date: EPA Reg No./ File Symbol Page 3 of 4 Applicant's/Registrant's Name and Address: Industrie De Nora S.p.A. c/o De Nora Tech 7590 Discovery Lane Concord, OH 44077 Ingredient: Sodium Chloride

Guideline Reference Number   Guideline Study Name	MRID Number	Submitter	Status	End Note
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			PL	1
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		Industrie De Nora	OWN	
			PL	2
			Waived	2
			Waived PL	2,3
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			Waived	2
			Waived	2
			PL	4
ignature: Jopa Bobba	Name and	Title: idula, BU General Manager	Dat	ruary 13, 2015

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DATA MATRIX			
EPA Reg No./ File Symbol	Page 4 of 4		
Product: Salt Cartridge for Giselle®			

- Reregistration Eligibility Decision (RED) Document, Inorganic Halides, List D, Case 4051 (Sept. 1993) and the Inorganic Halides Final Work Plan (FWP), Registration Review (Sept. 2009) lists the public literature that addresses these data requirements.
- 2. RED at 7 "Because of its abundance in the environment and low toxicity to humans, no toxicity data were required for sodium chloride." Similarly, FWP at 8, "Therefore, the Agency does not believe that further toxicity data or exposure assessments for sodium chloride will be needed in association with this registration review."
- 3. Sax, N. I., and Lewis, R. J. Sr., (1989) Dangerous Properties of Industrial Materials, 7th Ed.
- 4. Reregistration Eligibility Decision Document, Inorganic Halides, List D, Case 4051 (Sept. 1993) at 9. "Sodium chloride occurs abundantly in the natural environment. It is a component of seawater, and in the diets of most terrestrial animal. Although it can be toxic in large amounts, especially to freshwater aquatic organisms, the use of sodium chloride as registered will not result in any significant exposure to non-target organisms in the environment. For the currently registered uses, sodium chloride is present in low amounts, or is used in indoor situations only. Since sodium chloride readily dissolves, no environmental fate assessment was necessary. Therefore, the Agency does not require any environmental fate of ecological effect, data for sodium chloride." See also FWP at 13 for similar conclusions.

Signature:	Name and Title:	Date
Jopa Bhla	Giorgio Padula, BU General Manager	February 13, 2015

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#### VII. Letter of Authorization



January 27th, 2014

Via E-Mail

Mr. Demson Fuller
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Drive
2777 South Crystal Drive
Arlington, VA 22202-4501

Re: Authorization for EPA to Discuss FIFRA Registration Matters with Bergeson & Campbell. P.C., and The Acta Group

Dear Mr. Fuller:

Industrie De Nora S.p.A. (De Nora) authorizes the U.S. Environmental Protection Agency (EPA) to discuss information, including confidential business information, related to any De Nora proposed, pending, or active Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) registration or amendment application for any products, or any issue related to these De Nora registered products, with representatives of Bergeson & Campbell, P.C. (B&C\*) and its consulting affiliate, The Acta Group (Acta).

Additionally, EPA may forward information, including confidential business information, to B&C and Acta to the attention of Sheryl L. Dolan at the following address:

Sheryl Lindros Dolan The Acta Group 2200 Pennsylvania Avenue, N.W. Suite 100W Washington, DC 20037

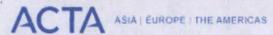
If you have any questions about this letter, please call me at +39 02 2129 2270, or Sheryl L. Dolan at (202) 266-5031.

Sincerely,

INDUSTRIE DE NORA S.D.A

Un Procuratore Giorgio Padula

### VIII. May 12, 2014, Letter to Demson Fuller from The Acta Group, *Industrie De Nora S.p.A.*, *December 3, 2013, Meeting Minutes*, resending the January 8, 2014, letter



May 12, 2014

Via Hand Delivery

Mr. Demson Fuller
U.S. Environmental Protection Agency
Office of Pesticide Programs (MC 7510P)
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Re: Industrie De Nora S.p.A. December 3, 2013, Meeting Minutes

Dear Mr. Fuller:

This letter and attachment follows up on our March 14, 2014, discussion concerning the above-referenced meeting minutes that were submitted to the U.S. Environmental Protection Agency (EPA) on January 9, 2014, by Industrie De Nora S.p.A.'s (De Nora) former agent, SciReg, Inc., for EPA's review, comment, and concurrence. As you will see, the attached minutes show EPA's pin-punch date stamp. De Nora is very concerned that the minutes appear to have been misplaced by EPA and not delivered to you, preventing your clarification on the issues discussed during the meeting. As De Nora is ready to submit its registration application, your immediate attention to this matter is urgently needed.

To facilitate EPA's review, The Acta Group (Acta) has outlined in this letter the issues and follow-up action items discussed in the minutes for ease of reference. Additionally, we request scheduling a meeting with EPA, with De Nora joining by teleconference, to discuss the follow-up action items. As during the meeting EPA stated it should be able to respond to the issues raised within two weeks, we suggest a meeting/teleconference during the week of May 27, 2014, if that could be scheduled.

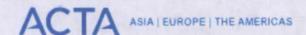
From the December 3, 2013, meeting, De Nora and Acta understand that EPA provided the following guidance concerning the proposed registration application, but please confirm:

{01243.002 / 111 / 00133381.DOC 6}

2200 Pennsylvania Avenue, N.W. Suite 100W Washington, D.C. 20037 TEL: 202/266-5020 FAX: 202/557-3836

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Mr. Demson Fuller May 12, 2014 Page 2

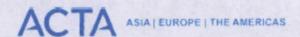
- De Nora must register the sodium chloride (NaCl) that will be sold and distributed with the sodium hypochlorite-generating equipment;
- De Nora must address the data requirements for NaCl. De Nora anticipates addressing these data requirements by:
  - Submitting five certificates of analysis for pharmaceuticalgrade NaCl for the preliminary analysis; and
  - Citing EPA's database for NaCl, which it describes as complete in its September 1993 Reregistration Eligibility Decision (RED) Document, Inorganic Halides and September 2009 Inorganic Halides Final Work Plan Registration Review document.
- De Nora must provide a preliminary or 5-batch analysis for the Soleva sodium hypochlorite solution produced by De Nora's equipment and NaCl. From the February 7, 2014, e-mail from Mark Perry, EPA, to Fred Smith, SciReg, we understand that these analyses must be conducted on five batches of both the 0.6 percent and 0.1 percent solutions, with each batch generated using a separate De Nora machine (so five batches total for each of the two solution concentrations).

In addition, De Nora requests EPA's clarification on the following issues, which were discussed at the December 3, 2013, meeting:

De Nora conducted several efficacy studies in 2012 and 2013 according to EPA's existing efficacy guidelines. Following EPA's December 6, 2013, new guidance specifying that testing must be conducted at the lower certified limit, De Nora has reviewed its studies. Most of the samples in these tests were tested at the lower certified limit or lower, given the concentration decline that occurs during the product's limited shelf life. In addition, Acta notes that in Reregistration Eligibility Document, Sodium and Calcium Hypochlorite Salts, 1 EPA states the following:

{01243,002 / 111 / 00133381.DOC 6}

EPA, Reregistration Eligibility Document, Sodium and Calcium Hypochlorite Salts (Feb. 1992) at 16.



Mr. Demson Fuller May 12, 2014 Page 3

The Agency has decided to continue its current policy of waiving the product-by-product efficacy data requirement normally levied on sanitizers and disinfectants for sodium and calcium hypochlorite formulations. The Agency has concluded that the published literature data can reasonably be extrapolated to the full range of these products.

In Na & Ca Hypochlorite Summary Document, Registration Review: Initial Docket, March 2012, EPA states that there are no outstanding data requirements for these active ingredients. Accordingly, if EPA determines at this time that De Nora must submit efficacy studies, De Nora requests EPA to accept its existing studies, which were completed before EPA published its revised guidance.

- As De Nora states clearly on its proposed label that the Soleva sodium hypochlorite solution is generated in single-use batches, and is effective only for 24 hours (for the disinfectant) or 48 hours (for the sanitizer), De Nora understands that EPA will require it to submit a storage stability study for the Soleva sodium hypochlorite solution but De Nora must conduct the study only for 48 hours. De Nora otherwise will follow the guidelines set forth in OCSPP 830.6317 for Storage Stability. As the sodium hypochlorite solution is stored in a plastic bottle for the 48 hours at room temperature conditions, we do not anticipate that testing will be required under the accelerated conditions in OCSPP 830.6313. Please confirm.
- De Nora understands that in its NaCl registration application, the only data requirements that it must address for the sodium hypochlorite solution are the preliminary analysis and storage stability studies discussed above. Please confirm.
- In response to EPA's request, De Nora will include information about the hardness of the tap water used during the efficacy studies. De Nora also plans to include in its application data that demonstrate that tap water with a range of mineral content/hardness does not affect the generation of the Soleva sodium hypochlorite solution by the De Nora equipment.
- During the December 3, 2013, meeting, Perry stated that he would research the quality control information provided by other similar product

(01243.002 / 111 / 00133381.DOC 6)



Mr. Demson Fuller May 12, 2014 Page 4

registrations and provide guidance to De Nora in this regard. De Nora appreciates and looks forward to this feedback.

During the December 3, 2013, meeting, De Nora discussed its interest in having the De Nora system tested with prospective customers in the United States on a limited basis to assess the case of use of the equipment. Perry stated he would research and provide guidance on this issue as well. De Nora requests EPA to provide it with an Experimental Use Permit (EUP) waiver for this select distribution and evaluation. Please advise what information EPA requires to grant the EUP waiver.

Finally, prior to the follow-up meeting, De Nora will provide EPA with a draft proposed label for review and discussion.

. . . . .

We hope this issues summary is helpful. We look forward to engaging with EPA to support this exciting new product. Please advise concerning a meeting/teleconference schedule, and as always, please call either me, at (202) 266-5031, or my colleague, Hank Jacoby, at (301) 865-9090, if you have any questions.

Sincerely,

Sneng Ludios Odan

Sheryl Lindros Dolan

Attachment

{01243.002 / 111 / 00133381 DOC 6}

#### SciReg, Inc. Science and Regulatory Consultants

January 8, 2014

Demson Fuller
Acting Team Leader (PM Team 32)
Antimicrobials Division, Regulatory Management Branch II
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Dr.
Arlington, VA 22202

Re: Meeting minutes; sodium hypochlorite-generating devices

Dear Mr. Fuller:

On behalf of De Nora Next S.p.A., SciReg, Inc. is submitting minutes from our December 3, 2013 meeting regarding EPA regulation, under FIFRA, of sodium hypochlorite-generating devices. Also attached are copies of the PowerPoint presentations discussed during our meeting.

Please note during your review of the minutes that there are a few outstanding issues for which we are awaiting input from the Agency. De Nora is anxious to initiate and expedite the registration of its salt cartridge product and would greatly appreciate the EPA's review of, and feedback on, the enclosed meeting minutes as soon as possible.

Thank you and the rest of the Agency participants for taking the time to meet with us last month.

Sincerely,

James S. Damico

President

Enclosures

12733 Director's Loop, Woodbridge, VA 22192 Telephone: (703) 494-6500 Facsimile: (703) 492-6600 www.SciReg.com

#### De Nora Next S.p.A. ("De Nora") Sodium Hypochlorite-Generating Device

Meeting Minutes December 3, 2013

#### Participants:

For U.S. EPA:

lain Blackwell (EPA/AD/PSB) Demson Fuller (EPA/AD) Mark Perry (EPA/AD) Marc Rindal (EPA/AD/EET)

For the applicant: Mara Bagnasco (De Nora)

Bob Blank (De Nora)

Jim Damico, Consultant (SciReg, Inc.)

Giorgio Padula (De Nora) Assunta Rossi (De Nora)

Fred Smith, Consultant (SciReg, Inc.)

#### Contains Confidential Business Information

This meeting was held to discuss the regulation under FIFRA of sodium hypochloritegenerating devices and the data requirements to support these products.

Introductions were made and an attendees list was circulated. The following materials were provided by SciReg and are attached herein:

- PowerPoint presentations 2
- J. Damico stated that SciReg is a consultant for De Nora. He added that, several months prior, he and Lance Wormell had discussed ways in which EPA may regulate sodium hypochlorite-generating devices, and today's meeting is intended to address a number of questions regarding sodium hypochlorite-generating systems.
- G. Padula briefly described De Nora, its global structure and its businesses. He added that De Nora's Giselle device produces sodium hypochlorite when water, salt, and electrical current are combined. M. Bagnasco discussed Giselle and explained its intended use to generate sodium hypochlorite, nominally at 0.1% and 0.6%, for on-site use for hard, nonporous surface sanitization and disinfection. Only spray application methods will be sought. The duration of electrolysis and the volume of water used dictate the sodium hypochlorite concentration produced. She added that the device is approximately the size

of a countertop coffee maker. The sodium hypochlorite solutions produced by Giselle are called Soleva.

M. Bagnasco described the device accessories, including the salt cartridges sold only for use in Giselle. The cartridges contain 80 grams of 99.95% pure salt (granular sodium chloride). Plastic bottles with blue and green labels (for the 0.1% and 0.6% sodium hypochlorite solutions, respectively) are also included. The sodium hypochlorite solutions are dispensed directly from Giselle into the appropriate bottle for on-site use only. There is no sale or distribution of the solutions. The bottles are labeled at the time of solution production with the date of production, the sodium hypochlorite concentration, and the product name (Soleva). It takes approximately 3-4 minutes to produce the 0.1% solution and approximately 10 minutes to produce the 0.6% solution. No stabilizers or other inert ingredients are added to the solutions. Stability is, therefore, limited to 24 hours (0.6% solution) or 48 hours (0.1% solution).

EPA asked if water hardness had been evaluated by De Nora relative to its effect on efficacy. M. Bagnasco stated that water hardness (using tap water) had been evaluated and there was no significant effect. De Nora's device is intended to be used with tap water. She added that the pH of the water used for efficacy testing was approximately pH 7. The Soleva solutions produced ranged from approximately pH 8.5-9.2.

EPA asked if the Soleva solutions were monitored in any way to confirm the sodium hypochlorite output concentrations. G. Padula responded that no such monitoring is necessary, as the device is electronically controlled to produce consistent concentrations. On-site maintenance of the Giselle devices will occur yearly, by De Nora technicians. Software updates will be provided, when needed.

De Nora added that it has evaluated the Soleva solution concentrations produced by Giselle under accelerated conditions (continuous production) that mimic multiple years of use. Two devices were used to produce each of the two solution concentrations.

- J. Damico discussed the requirement/non-requirement to register Giselle, the salt cartridge, and Soleva. He stated there are thousands of unregistered, on-site sodium hypochlorite generators on the market that operate in a manner very similar to Giselle. These devices use salt, water, and electrical current to produce the sodium hypochlorite solutions. Examples of such devices were included in Presentation 1 (see slide 12).
- J. Damico added that Giselle is produced in an EPA-registered establishment and that De Nora/SciReg is not aware of a single sodium hypochlorite-generating device that is registered by EPA. There are, however, two very recently registered products that are similar to De Nora's salt cartridge (Ecolab's Hydris Mineral Activator; EPA Reg. No.

1677-240; registered July 17, 2013), and the Soleva (Ecolab's Hydris; EPA Reg. No. 1677-241; registered September 17, 2013). He asked under what FIFRA section, EPA regulations, or other formal EPA policies these products were required to be registered. EPA did not provide such citations, but did provide an excerpt from an email that suggested EPA required registrations for other products in situations similar to Dc Nora's. [NOTE: after the meeting, SciReg reviewed the four products addressed in the email (EPA Reg. Nos. 82341-1, 85134-1, 86854-1, and 87518-1) and found there are key differences from the De Nora situation. The registered products are end-use sanitizing/disinfecting solutions presumably registered with EPA so that they can be packaged for further sale and distribution off-site. Neither the devices that produce the solutions, nor the salt/brine used in the devices to make the solutions, appear to be registered by EPA. The sodium hypochlorite solutions produced using the De Nora Giselle device will not be offered for further sale/distribution off-site.]

- D. Fuller stated that if "commodity" salt is used to generate the sodium hypochlorite solutions, the device itself needs to be produced in an EPA-registered establishment, but the salt is not required to be registered. If, however, a specific salt, such as one prepackaged in a salt cartridge, is used, the salt itself requires EPA registration. J. Damico asked if the device and the salt were not sold together was registration of the salt still required. D. Fuller responded that, if the salt cartridge contains salt when sold, the salt cartridge is required to be registered, even if sold separately from the device. J. Damico asked for EPA's policy/regulation that confirmed this requirement. D. Fuller indicated he will look into this issue and provide feedback to De Nora/SciReg.
- G. Padula added that the reason De Nora wants to sell its specific salt for use in the Giselle device is to ensure the quality and consistency of the sodium hypochlorite solutions produced.
- J. Damico stated that it was unclear why Hydris (i.e., a sodium hypochlorite solution) was required to be registered, as this raised the possibility that end users of the Hydris generator, such as hospitals, day care centers, schools, etc., would be producing a registered pesticide in unregistered establishments. This directly conflicts with EPA's regulations. D. Fuller responded that it was the Agency's understanding that Ecolab registered Hydris so that, if desired, it could be produced in EPA-registered establishments, then offered for sale and distribution.
- G. Padula asked if any registrations would still be required if Giselle was leased to facilities, instead of selling the devices to them. M. Perry responded that leasing is considered to be the same as selling.

M. Perry asked how the salt concentration in the water is determined. G. Padula responded that the water/salt solution is produced inside Giselle on-demand whenever the Soleva solutions are produced. The volume of water used by Giselle and the duration of electrolysis dictate the sodium hypochlorite solution concentration. He added that the volume of Soleva dispensed by Giselle is automatically regulated by the device. The Soleva pH remains relatively constant, while the sodium hypochlorite concentration decreases but maintains the required efficacy level over 24-48 hours post-production.

Based upon the foregoing discussion, J. Damico stated it was SciReg's understanding that the Giselle device will not require EPA registration; however, the salt cartridge will require registration. Further, the device and salt needs to be produced in an EPA-registered establishment. He added that if Soleva will not be sold or distributed, EPA registration is not required and, as such, producers (i.e., end users) of Soleva will not need to register their facilities as pesticide production establishments. EPA confirmed this. D. Fuller added that EPA will require efficacy data to be submitted on the Soleva solutions, even if the solutions are not registered. Also, it is understood that some individual U.S. states may require the device to be registered, even if EPA does not.

- J. Damico discussed the data requirements to support the salt registration (see Presentation 2). He indicated that De Nora intended to address the same data requirements for its salt cartridge that Ecolab submitted for its Hydris Mineral Activator Tablet (Group A and Group B product chemistry, except that a boiling point study will not be submitted).
- I. Blackwell asked how De Nora intended to satisfy the acute toxicology requirements for the salt. J. Damico stated that it did not appear from a National Pesticide Information Retrieval System (NPIRS) database search that Ecolab submitted such data. However, it is likely De Nora will satisfy these data requirements via a combination of open literature or other studies on table salt, and written discussion on the lack of user exposure to the salt due to the manner in which it is packaged and used.
- I. Blackwell asked if De Nora will be seeking Toxicity Category 4 label language. J. Damico stated that Toxicity Category 3 text will likely be acceptable. M. Bagnasco added that the salt used in De Nora's salt cartridges is pharmaceutical grade. G. Padula stated it is produced in an FDA-regulated establishment.
- J. Damico asked if any other data requirements on the salt needed to be addressed by De Nora. D. Fuller confirmed that, other than product chemistry and acute toxicology, no other data are needed on the salt.

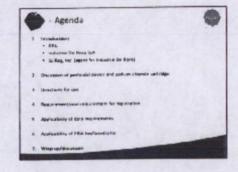
- M. Perry discussed the Agency's efficacy requirements. He stated that the data needed to be developed using the lower certified limit for sodium hypochlorite (i.e., the lowest acceptable limits of sodium hypochlorite present in the 0.1% and 0.6% solutions). He added that both Soleva concentrations (0.1% and 0.6%) were to be evaluated at the lower limit. Stability data on both solution concentrations are also required to be submitted; these data are also to be developed at the lowest acceptable limit for both solutions at 24 and 48 hours post-production.
- J. Damico asked if storage stability and corrosion characteristics data on the salt could be submitted as conditions of registration. D. Fuller stated that he will confirm the applicable product chemistry requirements with J. Negron (EPA chemist) and provide feedback to De Nora/SciReg.
- M. Perry stated that he will check on other similar product registrations regarding the quality control information that needs to be submitted, and will provide feedback to De Nora/SciReg within approximately two weeks. M. Bagnasco added that one of every ten Giselle devices is checked for quality control.
- D. Fuller asked how the cartridge label would appear on the product. G. Padula stated the label would likely be a fold-out type, since the packaging for the salt cartridges is so small. J. Damico added that the label content will be modeled after Ecolab's Hydris Mineral Activator Tablet label.

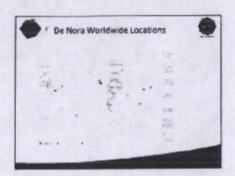
Discussion followed regarding the proposed PRIA category for registration of the salt. D. Fuller indicated that category A540 (5 months; \$4,863) is appropriate.

- M. Bagnasco asked what De Nora is permitted to tell its distributors regarding the proposed sodium hypochlorite-generating system prior to registration. D. Fuller stated that distributors can test the system, but it cannot be sold to them. The associated label cannot make any pesticidal claims. The system can be evaluated in food-handling establishments. B. Blank asked if the De Nora system could be tested by universities for usability, not efficacy. M. Perry stated that he will check on this and provide feedback to De Nora/SciReg. B. Blank added that the devices would be provided free of charge to facilities for evaluation.
- J. Damico indicated that SciReg will prepare and submit meeting minutes to D. Fuller. De Nora will coordinate the registration application and direct any/all inquiries to D. Fuller in order to streamline and expedite the process.

#### Presentation 1



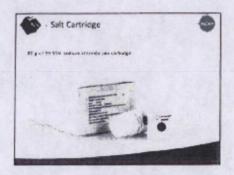




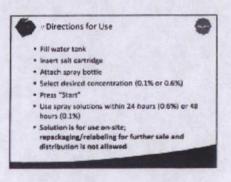


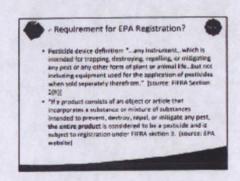


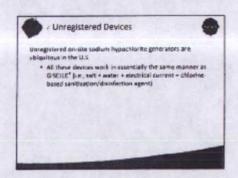






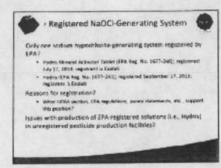


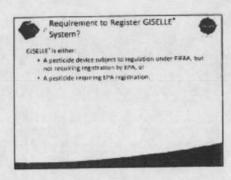


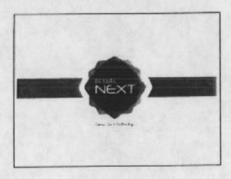




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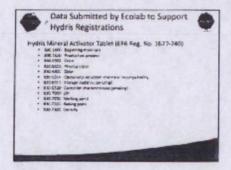


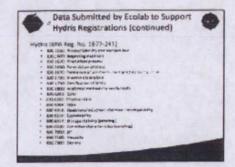


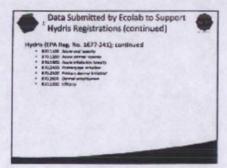


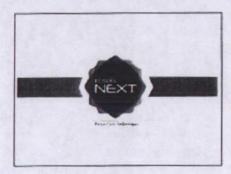
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#### Presentation 2









### IX. E-mail Correspondence between Demson Fuller and Mark Perry, EPA, and SciReg, Inc.

 From:
 Fuller, Demson

 To:
 Sheryl L. Dolan

 Subject:
 FW: De Nora - follow up

Date: Friday, March 14, 2014 4:23:38 PM

fyi

From: Perry, Mark

Sent: Friday, February 07, 2014 9:47 AM

To: Fred Smith Cc: Fuller, Demson

Subject: RE: De Nora - follow up

Fred,

Very sorry for the late response; your emails have been automatically routed to my junk mail box. I have corrected this and informed Demson of the problem in case he is having the same issue. Regarding your questions, we would like each batch to be generated with a different unit (5 units, each used to generate a .6 and a .1% sample). Regarding the LCL question, I need some clarification... when in 2012 was the study initiated and are all test material concentrations below the nominal?

Mark Perry Antimicrobials Division US EPA

From: Fred Smith

Sent: Tuesday, December 24, 2013 7:03 AM

To: 'Perry, Mark' Cc: 'Fuller, Demson'

Subject: RE: De Nora - follow up

Mark-

In addition to our question below, we have one more that was briefly raised during our Dec. 3 meeting. We understand that efficacy data are now to be developed using the lower certified limit for the AI, per the Agency's guidance that was published on Dec. 6, 2013. De Nora developed its efficacy data on its sodium hypochlorite solutions (Soleva) in 2012 under the then-current EPA guidelines. We want to make sure that the Agency's new requirement will not affect the validity of De Nora's 2012 testing. Please confirm.

Thanks very much.

Kind regards,

--Fred

From: Fred Smith

Sent: Monday, December 16, 2013 12:42 PM

To: 'Perry, Mark' Cc: 'Fuller, Demson' Subject: RE: De Nora - follow up

Hello, Mark-

Just following up on my Dec. 6 email below. Thoughts?

Thanks.

--Fred

From: Fred Smith

Sent: Friday, December 06, 2013 10:10 AM

To: 'Perry, Mark' Cc: 'Fuller, Demson'

Subject: De Nora - follow up

Mark-

As follow up to our meeting on Tuesday regarding De Nora's sodium hypochlorite-generating device, we have a question concerning the 5-batch analyses. We understand that analytical results from 5 batches each of the 0.1% solution and the 0.6% solution are required. Our question is can 5 batches of each solution concentration be generated and analyzed for the same device or do we need to generate and analyze each batch from a separate device? It seems to us that either route is acceptable.

Please let us know. Thanks very much.

Fred

Frederick T. Smith Senior Regulatory Specialist SciReg, Inc. 12733 Director's Loop Woodbridge, VA 22192 USA Phone: (703) 494-6500

Phone: (703) 494-6500 Fax: (703) 492-6600 www.SciReg.com

### X. July 21, 2014, Letter to Demson Fuller from The Acta Group, EPA AD and Industrie De Nora July 9, 2014, Meeting and Follow-Up, and cover e-mail



July 21, 2014

Via E-Mail

Mr. Demson Fuller
U.S. Environmental Protection Agency
Office of Pesticide Programs (MC 7510P)
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Re: EPA AD and Industrie De Nora July 9, 2014, Meeting and Follow-Up

Dear Demson:

On behalf of Industrie De Nora S.p.A. (De Nora), The Acta Group (Acta<sup>6</sup>) thanks you for the July 9, 2014, meeting. We found the information exchange helpful and hope that the U.S. Environmental Protection Agency (EPA) Antimicrobials Division (AD) did as well. We summarize below the main discussion points from the meeting, including the two issues that required further discussion within AD, which appear in bold face. We look forward to your response on these issues. We have attached the draft proposed label in connection with this follow-up.

- Certificates of analysis provided by the supplier of the pharmaceutical grade sodium chloride for five separate batches, along with an explanation of why these analyses are sufficient for AD's purposes, will suffice to meet the preliminary analysis requirement.
- EPA has requested analyses of the 0.6% and 0.1% solutions generated by five separate Giselle machines for confirmation of the sodium hypochlorite concentrations; additional analyses similar to those conducted for a preliminary analysis, such as for impurities, are not required.
- For the analyses of the 0.6% and 0.1% solutions, commercial reagents and test standards were used that were supplied according to commercial specifications. Accordingly, these standards were not separately validated. We expect this is acceptable but AD has agreed to discuss and respond.

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Mr. Demson Fuller July 21, 2014 Page 2

- As the efficacy studies contain sodium hypochlorite concentration data for the periods for which the product will be claimed as efficacious (24 and 48 hours), De Nora will cite these studies to support the storage stability statements. De Nora also will cite EPA's database to address the storage stability of sodium chloride.
- The 0.6% disinfectant and 0.1% sanitizer bottles will be different colors and labeled with appropriate use directions. A printer integrated with the Giselle equipment will print out the date and time of batch production, so the user knows by when the solution must be used. AD agreed to review the draft labeling, including the bottle labeling, and consider whether a master label-type format or another approach should be used. AD stated the Giselle user manual also must be
- AD reiterated its prior inquiry about the effects of hard water on product efficacy and asked De Nora to submit data to address this issue. De Nora reports water hardness in European units and will comply with AD's request to convert those units into parts per million (ppm) equivalents as calcium carbonate.
- In response to AD's inquiry about quality control for the Giselle machine, De Nora stated that for each batch, internal monitoring controls the production process parameters for voltage, current, and electrolysis time to confirm the selected sodium hypochlorite concentration is correct. During product development, De Nora conducted extensive lifecycle testing on the Giselle machines to confirm consistent and reliable batch production over the life of the machine. Additionally, Giselle is programmed to require cleaning every 80 production cycles and calibration every 100 cycles.
- AD agreed to review and consider the Experimental Use Permit (EUP) exemption request upon submission and respond timely.

De Nora appreciates AD's ongoing assistance and looks forward to AD's response. As always, please call if you have any questions.

Sieng Lindle Dolan

Sheryl L. Dolan

Attachment

Mr. Lance Wormell (w/attachment) (via e-mail)

Mr. Mark Perry (w/attachment) (via e-mail)

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